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Supreme Court, U. S.
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IN THE

Supreme Court of the United States

OCTOBER TERM, 1974

No. 74-1383

NATIONAL NUTRITIONAL FOODS ASSOCIATION and SOLGAR CO., INC.,

Petitioners,

—against—

CASPER W. WEINBERGER, Secretary of Health, Education and Welfare, and ALEXANDER M. SCHMIDT, Commissioner of Food and Drugs,

Respondents.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

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CASPER W. WEINBERGER, Secretary of Health, Education and Welfare, and ALEXANDER M. SCHMIDT, Commissioner of Food and Drugs,

Respondents.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

Petitioners pray that a writ of *certiorari* issue to review the judgment of the United States Court of Appeals for the Second Circuit, entered in the above-entitled case on February 3, 1975.

Citations to Opinions Below

The opinion of the Court of Appeals is set forth in Appendix A and has not yet been officially reported. The opinions of the District Court are set forth in Appendices B and C and have been officially reported at 366 F. Supp. 1341 (S.D.N.Y. 1973) and 376 F. Supp. 142 (S.D.N.Y. 1974).

Jurisdiction

The judgment of the Court of Appeals was entered on February 3, 1975. The jurisdiction of this Court is invoked under 28 U.S.C. §1254(1).

Questions Presented

1. Whether the decision of this Court in *Abbott Laboratories* v. *Gardner*, 387 U.S. 136 (1967), allowing pre-enforcement judicial review of interpretive regulations under §701 (a) of the Federal, Food, Drug, and Cosmetic Act, was intended to deprive litigants of their prior statutory right to either an administrative or judicial factual hearing on the merits with respect to criminal and civil enforcement sanctions under the Act?

2. Whether §503(b)(1)(B) of the Federal, Food, Drug and Cosmetic Act [21 U.S.C. §353(b)(1)(B)] authorizes a requirement that drugs be limited to prescription sale merely because an otherwise safe product can be deliberately and irrationally misused even in the face of cautionary labeling?

Statutes Involved

Statutory provisions of the Federal Food, Drug, and Cosmetic Act involved herein are §§503(b) [21 U.S.C. §353(b)], 701(a) [21 U.S.C. §371(a)], and §701(e) [21 U.S.C. §371 (e)]. Also involved are provisions of the Administrative Procedure Act at 5 U.S.C. §§553 and 706. These statutes are set forth in Appendix D.

Statement of Policy Under Review

The agency statement of Policy and interpretation at issue herein is officially set forth at 21 C.F.R. §§3.94-3.95 and is printed in Appendix E.

Statement

The instant petition presents important legal questions arising under the Federal Food, Drug, and Cosmetic Act (hereafter the "Act"), 21 U.S.C. §§301 *et seq.* At issue is a ruling by the Court of Appeals which drastically alters the entire structure of the Act, as designed by Congress. In brief, the Court of Appeals ruling so interprets the decisions of this Court as to allow the agency to promulgate binding substantive regulations under §701(a) of the Act without a hearing, without any judicial evidentiary inquiry, and without a showing of "substantial evidence" to support the agency's controversial action. This ruling means that the agency no longer need issue civil and criminal complaints of alleged violations of the statute, involving the subsequent rights to trials with witness and cross-examinations with the agency having the burden of proof on the merits. Instead, the agency can resort to the issuance of regulations under §701(a) of the Act which are subject to judicial review only under the "arbitrary or capricious" standard. In the instant case, the application of this new rule of law would permit the withdrawal from the marketplace of vitamins A and D products in quantities exceeding 10,000 and 400 international units (IU) respectively, by way of an imposition of a prescription requirement for these products.

Vitamins A and D have been sold ever since 1938 as foods for special dietary use under the Act. §403(j) [21 U.S.C. §343(j)]. On December 14, 1972, the Food and Drug Administration published a notice entitled "Vitamin A and D; Proposed Statement of Policy" (37 F.R. 26618). The proposal outlined a prescription requirement for products containing vitamins A and D in excess of 10,000 and 400 I.U. respectively, on the purported basis that unspecified "high dosages of such vitamins were known to be toxic." The only cited factual support for this proposal was a bare reference to a list of articles in the literature regarding these vitamins and their supposed toxicity (37 F.R. 26618, col. 1). No analysis of the literature was referred to or made public by the agency. Sixty days were allowed for the submission of *comments* by interested persons.

The proposed Statement of Policy evoked massive opposition from both industry and consumers. Many analyses of the literature were submitted to the agency and all concluded that the prescription levels in the proposed Statement of Policy were not supported by the available evidence and literature. Comments supporting the agency position were limited to letter endorsements without scientific analysis. Nevertheless, on August 2, 1973, the agency, in reliance on the letter endorsements and the above-mentioned articles[1] published its statement of general policy or interpretation on the status of vitamin A

[1] In response to the extensive analyses submitted, the agency without explanation, merely stated that "Such comments do not sufficiently support a revision of the proposed limits" 38 F.R. 20717, col. 2 (August 2, 1973).

and D by imposing the prescription requirements for all products labeled after October 1, 1973.

Petitioners commenced this action shortly thereafter seeking pre-enforcement, declaratory and injunctive relief with respect to the aforementioned Statement of Policy. The United States District Court for the Southern District of New York granted the agency's motion for summary judgment holding that petitioners were not entitled to a trial on the controverted factual issues raised, the agency action need not be supported by substantial evidence, that the prescription statute authorized the contemplated restrictions on products merely for the purpose of preventing deliberate abuse, and that in general the agency action was not "arbitrary or capricious." The United States Court of Appeals for the Second Circuit upheld the rulings of the District Court, herein at issue, and ordered a remand on the question of whether the products at issue could be considered "drugs" under the Act. The latter issue is not involved in the instant petition. The jurisdiction of the Court of Appeals in this matter was based on 28 U.S.C. §1291.

Reasons for Granting the Writ

Petitioners respectfully submit that *certiorari* should be granted herein to resolve an important and recurring question basic to the implementation of every aspect of the Federal Food, Drug, and Cosmetic Act. The opinion of the Court of Appeals erases long-standing distinctions between interpretive and substantive agency action. Involved is the status of literally scores of agency pronouncements and regulations each year which are issued under §701(a) of the Act, affecting the entire food, drug and cosmetic indus-

tries in the United States. Recently, the agency has shown an increased reliance on this regulatory approach, in some cases deliberately bypassing the more formal procedures specified under other statutory sections.[2]

In light of the utmost importance of definitively resolving the procedural and substantive status of these agency actions which affect the day-to-day health, safety and comfort of all citizens, it is hoped that Respondents will agree that the public interest urgently warrants the exercise of review by this Court as to this vital issue, presented to this Court for the first time.

In addition, the instant petition presents for review the related question of the scope of the prescription requirements under the Act. Involved, is the nature of the agency's authority to, in effect, withdraw products from the marketplace without a hearing by imposing prescription status despite the fact that the products do not require supervision of a physician when used in accordance with ordinary and appropriate cautionary labeling. Here, too, the opinion of the Court of Appeals seriously impairs the status of all drugs long sold over the counter in line with long-established congressional intent.

I.

Petitioners' grievance was succinctly summarized and recognized by the Court of Appeals as follows:

> "Appellants . . . contend that the FDA has no authority to issue regulations having the binding effect of law, other than those regulations which must be issued

[2] See, e.g., 39 F.R. 20895, June 14, 1974, proposing limitations on the contents of "breakfast drinks" under §701(a) despite the specific applicability of §701(e) of the Act.

under the adjudicatory hearing procedures provided by §701(e) of the Act, 21 U.S.C. §371(e).

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If this case had been one governed by hearing requirements like those in §701(e) or if the district court had held a *de novo trial,* appellants argue, crucial factual issues would have been resolved in their favor. They allege that they would have demonstrated that Vitamins A and D at the dosage levels specified in the regulations are not 'drugs' as that term is defined in §201(g) of the Act, 21 U.S.C. §321(g), because they were not intended for use in the treatment or prevention of disease but as dietary supplements, and that they could not lawfully be classified as 'prescription drugs' under §503(b)(1)(B) of the Act, 21 U.S.C. §353 (b)(1)(B), since the products are not toxic at the levels established by the regulations and are not inherently unsafe when used without prescription in a rational manner, but can become unsafe only when misused or used irrationally" (A 8-10).

A. *The Distinction Between Substantive and Interpretive Agency Action*

Congress, in enacting the Federal Food, Drug, and Cosmetic Act, was keenly aware of the distinction between substantive and interpretive agency action and structured the regulatory authority under the Act accordingly.[3] The Court of Appeals, however, totally failed to take this long

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[3] In explaining the need for detailed procedures under §701(e), the legislative history points out that these were intended to be binding and not "merely interpretive." H. Rep. No. 2139, p. 12, 75th Cong., 3d Sess. (1938). See also n. 7 at (A 11).

recognized and congressionally sanctioned distinction into account (A 13).

Substantive rule-making involves a statutory grant of authority to an agency to make policy or factual determinations which are ultimately to have the force and effect of law. Interpretive agency action is *by definition* not binding upon the courts and the parties adversely affected can challenge them in enforcement proceedings. The Administrative Procedure Act makes a sharp distinction between these two types of agency action. See 5 U.S.C. §551(4)-(5) and 5 U.S.C. §553(b). The basis of the distinction is the binding nature of substantive regulations as opposed to the only pursuasive authority of interpretive agency action.[4] *Skidmore* v. *Swift & Co.*, 323 U.S. 134 at 140 (1944); *Gibson Wine Co.* v. *Snyder*, 194 F.2d 329 at 331-332 (D.C. Cir. 1951); *American President Lines, Ltd.* v. *Federal Maritime Commission*, 316 F.2d 419 at 422 (D.C. Cir. 1963); *O'Neill* v. *United States of America*, 281 F. Supp. 359 at 363 (D. Ohio 1968) aff'd 410 F.2d 888 (6th Cir. 1969); *Matczak* v. *Secretary of HEW*, 299 F. Supp. 409 at 412, n. 4 (E.D.N.Y. 1969); *Continental Oil Co.* v. *Burns*, 317 F. Supp. 194 at 200 (D. Del. 1970); *Soriano* v. *United States*, 494 F.2d 681 at 683 (9th Cir. 1974). See also Davis, *Administrative Law Treatise* (1958) §5.03-.05; 1970 Supplement to Treatise §5.03-.04.

This distinction is precisely mirrored by the two types of regulations noted in §701 of the Act. Section 701(e) sets forth a fully detailed procedure for agency promulgation

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[4] See legislative history of Administrative Procedure Act, House Report No. 1980, 79th Congress, 2d Section at p. 18, and Report of Attorney General's Committee on Administrative Procedure (1941).

of various factual determinations for the purpose of establishing regulations. These include due process protections with the right to a hearing and cross-examination of witnesses. For example, the agency under §701(e) and §401 [21 U.S.C. §341] has authority to implement this regulatory procedure with respect to standards of identity for food products. Full judicial review on a substantial evidence basis is provided in the Court of Appeals. See, e.g., *National Nutritional Foods Association* v. *Food and Drug Administration,* 504 F.2d 761 (2d Cir. 1974) which, after careful review of a lengthy factual record, affirmed in part, reversed in part and remanded in part. Under this procedure, products sold in violation of a standard of identity are specifically made subject by the statute to criminal and civil enforcement sanctions. See §403(g) [21 U.S.C. §343 (g)].

On the other hand, §701(a) of the Act does not specify any procedure. Under this section, the agency has long published statements of policy and interpretation for the purpose of advising the public as to how the agency intends to enforce the Act. For example, §402(a)(4) of the Act [21 U.S.C. §342(a)(4)] provides that a food is adulterated and, therefore, subject to criminal and civil proceedings if the food was prepared in a manner which was not in accordance with "good manufacturing practice." The Food and Drug Administration issued an interpretive regulation with respect to the "good manufacturing practice which specifically and precisely established guidelines for the entire manufacturing process for smoked fish.[5] In *United States of America* v. *Everett Fisheries, Inc.,* 72 C.R. 109

[5] 21 C.F.R. 128a, subpart A.

(W.D. Wisc. May 30, 1973)* the court held with respect to such interpretive regulation:

> "[I]n each case the government must present its evidence so as to persuade the finder of fact *and the defense must have its opportunity to dispute* and that the judgment exercised by the Food and Drug Administration in promulgating regulation 128a, Subpart A is not to be given automatic and decisive effect in the case; rather, that the regulations in question are to be given just such effect as the trier of fact may consider that they deserve on the basis of the evidence in the case" (Appendix F, 3-4). (Emphasis added.)

It has long generally been thought that agency pronouncements under §701(a) of the Act were within the aforementioned interpretive category. See Munsey, *Survey of Current Legal Problems in the Drug Area*, 23 Food, Drug and Cosmetic L.J. 449 at 454 (1968) and Cody, *Authoritative Effect of FDA Regulations*, 24 Food, Drug and Cosmetic L.J. 195 at 196 (1969). In fact, the agency itself took that position before this Court in *Abbott Laboratories* v. *Gardner*, 387 U.S. 136 (1967) for the purpose of trying to prevent pre-enforcement judicial review. This Court held, however, that even though interpretive agency action was not binding in the strict sense, it did present a justiciable controversy to the extent that it imposed on the affected members of the public the dilemma of either complying with the agency action or risking severe sanc-

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* This unreported decision appears to be the only case in which the effect of a §701(a) agency action was adjudicated in the context of a governmental claim that the regulation was binding. The entire opinion is reproduced in Appendix F.

tions in enforcement proceedings. This Court therefore endorsed pre-enforcement judicial review as an expeditious alternative method of determining the validity of interpretive action by way of a declaratory suit. 28 U.S.C. §1201.

The decision of the lower court herein, however, holds that as a consequence of the decision in *Abbott Laboratories* the previous right to a full factual judicial inquiry in enforcement proceedings has been lost.[7] As a result, *Abbott Laboratories*, instead of expanding the availability of judicial review to pre-enforcement situations, will have the opposite result of limiting judicial review without a full factual inquiry.

The other cases cited by the Court of Appeals also seriously misinterpret the decisions of this Court. In *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973), the Court upheld an agency policy under §701(a) of the Act which provided that a factual hearing need not be given for the withdrawal of new drug applications under the Act where the studies submitted in support of the efficacy of this drug on their face, did not comply with the undisputed statutory requirements for controlled studies. The Court, therefore, upheld the agency's interpretation of the statute as to when a hearing was required and allowed the use of a summary judgment procedure where there was no conflict as to the facts. This Court never ruled that under §701(a) an agency could withdraw products from the market without any hearing even where, as in the instant case, serious controversy exists and was presented as to the facts.

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[7] Actually in *Abbott Laboratories* this Court noted that there was no issue of fact to be resolved in that case. 387 U.S. at 149.

Since the decisions of this Court have been cited and relied on for propositions which were not raised or presented therein, it is of great importance that this Court resolve these questions in light of the serious prejudice to the public arising from the denial of any judicial factual inquiry.[8]

B. *The Court of Appeals' Decision Destroys the Carefully Designed Structure of the Federal Food, Drug, and Cosmetic Act*

The Federal Food, Drug, and Cosmetic Act was carefully balance and integrated with respect to the interplay of regulatory and enforcement functions. The Act imposes severe criminal and civil penalties and provides for harsh seizure and injunctive enforcement remedies. [§§301, 302, 303 and 304 (21 U.S.C. §§331, 332, 333 and 334)].[9] Consequently, Congress was very careful to insure that these sanctions would not be imposed without a prior evidentiary administrative or judicial hearing. The Act provides for various types of regulatory procedures with respect to determining factual questions as to the safety, effectiveness and wholesomeness of various products. Every factual agency determination under the statute which may have the result of adversely affecting or imposing sanctions on members of the public is governed by either the specific

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[8] Compare, *Salazar* v. *Hardin*, 314 F. Supp. 1257 (D. Colo. 1970), where a full trial was had with respect to an interpretive regulation of another agency.

[9] In fact, in the case of *United States* v. *Park* recently argued before this Court under Docket No. 74-215, the FDA has taken the position that corporate officers may be convicted under the criminal sanctions of the Act even without a finding of particular acts of either omission, commission or gross negligence under the rule of *United States* v. *Dotterweich*, 320 U.S. 277 (1943). These harsh sanctions would now be imposed automatically for violation of a §701(a) agency pronouncement without any opportunity for a factual hearing as to the disputed merits of the agency's position.

hearing provisions of §701(e) of the Act or else a separate and specific statutory hearing and judicial review structure.

Under the statute, such items as the classification of new drugs [§505 (21 U.S.C. §355)], certification of antibiotics [§507 (21 U.S.C. §357)], and establishment of rigorous standards of identity for food products [§§401 and 701(e) (21 U.S.C. §§341 and 371(e)], are governed by specific and precise evidentiary hearings followed up by a "substantial evidence" standard of judicial review, either in a United States Court of Appeals or a United States District Court. Congress, in the Federal Food, Drug, and Cosmetic Act, clearly recognized that factual questions involving the public health, safety and comfort could only be resolved on a factual basis and not by mere dictation of agency policy. In each case where substantive regulatory authority is given to the agency, it is governed by full evidentiary proceedings and accompanying due process protections. Moreover, substantive agency regulation is expressly and specifically integrated into the enforcement and criminal sanctions of the Act. Congress, however, has nowhere made it a crime to violate an agency pronouncement under §701(a) of the Act, and yet the Court of Appeals would permit the imposition of these severe sanctions without any of the due process protections built into the statute. The effect of the Court of Appeals decision would be to allow the agency to bypass its statutory burdens in enforcement proceedings. Instead of issuing a complaint, the agency could now merely issue a pronouncement under §701(a) of the Act inviting comments and then adhere to its original announcement as not arbitrary or capricous.[10]

[10] In the instant case, the agency relied on its earlier opinion without any detailed factual explanation.

The legislative history of the Act clearly shows that in establishing the distinction between §701(a) and §701(e) agency action, Congress was referring to the traditional distinction between interpretive and substantive regulations as outlined above. Any doubt on this score is resolved by the House Report which discusses the regulatory authority under the Act and notes:

> "§701 relates generally to regulations. In the case of regulations, the violation of which constitutes an offense, it is required that appropriate notice of a public hearing be given and that adequate time shall be given after the promulgation of a regulation before it becomes effective." Report No. 2139, House of Representatives, 75th Congress, 3rd Session, pp. 11-12: Dunn, The Legislative History of the Federal Food, Drug, and Cosmetic Act, p. 823.

The Congressional intent was therefore expressly indicated to the effect of insuring that the civil and criminal penalties of the Act should not be imposed without a full evidentiary hearing.[11] The §701(a) authority necessarily was intended to deal with interpretive agency action which would in any event be subject to full judicial review avoiding the need for any separate statutory hearing procedure. The Court of Appeals ruling that §701(a) agency action is substantive and subject only to review under the narrow arbitrary and capricious standard, will have the effect of drastically altering the nature and function of the statutory criminal and enforcement provisions. When-

[11] It is simply beyond belief that Congress required, for example, a full evidentiary hearing for informational labeling under §403(j) and §701(e) while permitting the withdrawal of products from the market under §701(a) without any fact finding procedure.

ever, in the agency's opinion, a violation of the statute exists, the option of enforcement procedures and the concomitant factual evidentiary burdens are available to the agency. Now these burdens can simply be bypassed by resorting to a §701(a) regulation under which the agency's opinion will be upheld if it is not arbitrary and capricious. In the instant case, the lower courts simply deferred to the agency's "expert" opinion (except for the partial remand), thereby frustrating any meaningful judicial review.[12]

The essential element overlooked by the Court of Appeals is the specific Congressional intent and design in enacting the Food, Drug, and Cosmetic Act. Judge Lumbard, although concurring, expressly noted his serious reservations as to whether Congress ever intended the instant agency action to be substantive (A 30). His concurrence was based on the assumption that this Court would, in any event, uphold the regulations. Both the majority opinion and the decision of the District Court rely on trends involving other administrative agencies without giving paramount consideration to the Congressional structure of the Food and Drug Act and clear legislative intent discussed above. This Court should resolve this issue in the interest of finally determining and resolving the status of these increasingly resorted to §701(a) agency pronouncements.

C. *Congress Expressly Sought to Preclude Substantive Agency Authority Under the Prescription Statute*

Any remaining doubt as to the Congressional intent is resolved by the legislative history of the prescription stat-

[12] The Court of Appeals actually went so far as to state that it was relying on the agency's general, although unexplained, assessment of the purported dangers of vitamins A and D (A 21).

ute at issue herein. The prescription statute in §503(b)(1)(B) of the Act [21 U.S.C. §353(b)(1)(B)], unlike other statutory sections, does not make provision for substantive regulations. In fact, the specific legislative history shows that Congress expressly refused to give the agency such authority.[13]

Prior to the enactment of §503(b)(1)(B), there was no provision or standard in the statute specifically governing prescription drugs. Prescriptions were required if such was necessary as part of the more general requirement for adequate directions for use on all drug products under §502(f)(1) [21 U.S.C. §352(f)(1)]. The agency did however, promulgate an interpretive regulation specifying its views as to prescription requirements. See 21 C.F.R. §2.106(b)(1) and (b)(2)(ii) (1944 Supp.).

The original prescription statute as first proposed in the House of Representatives would have given the agency substantive grant of authority to determine prescription status (97 Cong. Rec. 9334, cols. 1 and 2). This would have involved a full hearing procedure similar to that which is found in §701(e) of the Act. After serious objections were raised to this grant of authority, the House of Representatives passed the O'Hara Amendment which incorporated into the statute the standard which had previously been contained in the agency's interpretive regulation with en-

[13] It is interesting to note that with respect to habit-forming drugs covered by §503(b)(1)(A) and new drugs covered by §503(b)(1)(C) [21 U.S.C. §§353(b)(1)(A) and (b)(1)(C)] there is substantive statutory authority for determining prescription status. See also, 21 U.S.C. §352(d). Ironically, the result of the Court of Appeals' decision will be to make it easier for the agency to classify "old drugs" for prescription than the more dangerous "new drugs" and habit-forming drugs.

forcement in the courts available to determine if the statutory standard had been violated. The Congressional debates clearly show the express purpose of preserving a full factual judicial inquiry as to whether a prescription classification is appropriate.[14] After passage in the House, the bill was sent to the Senate where a bill similar to the original House bill was pending. The Senate Committee accepted the final House version and recommended it for passage. There was no debate in the Senate and the bill was passed. The Senate Committee Report notes:

> "As previously stated, the committee considered S. 1186 together with H.R. 3298. S. 1186 would have authorized the Federal Security Administrator to list by name or class the drugs which he considered within the statutory definition. The grant of such administrative authority was objected to as an unnecessary regulation of the drug industry, and the committee concluded that administrative listing is not necessary at this time. *It was felt that the statutory definition, together with the authority to make interpretive regulations, could bring an end to the existing confusion in drug labeling and that uniformity can be achieved through cooperative efforts of the drug industry and the Food and Drug Administration* working under the statutory plan." Senate Report, No. 946, 82nd Congress, 1st Session, pp. 4-5. (Emphasis added.)

It is therefore apparent that Congress expressly refused to grant the agency substantive authority with respect to

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[14] The full debates took place on July 31 and August 1, 1951 and appear at 97th Cong. Rec. 9235-9243, 9321-9349. The vigorous debate shows beyond any doubt the express intent to bar any binding prescription authority for the agency.

prescription requirements. Instead, the Senate Committee suggested that the agency resort to *interpretive* regulations under §701(a) and, in fact, categorized such regulations as interpretive at least four times.[15] The holding of the Court of Appeals frustrates the specific Congressional intent with respect to prescription status. Here, the agency simply stated that in its opinion prescription status was appropriate and the lower courts have deferred thereto. Congress specifically sought to avoid this result by removing any grant of substantive authority to the agency.

D. *The Application of the Arbitrary and Capricious Standard of Review Frustrated Any Meaningful Judicial Review*

In addition to holding that the agency has substantive authority under §701(a) of the Act, the lower court also ruled that review of such agency action is limited to the arbitrary or capricious standard of review. 5 U.S.C. §706 (a). Under this approach, the court was able to uphold the regulations (except for the partial remand) despite the fact that the agency presented no more than a few letter endorsements and unanalyzed articles as factual support for its position. Presumably, the theory is that the agency action is not arbitrary and capricious since it relied on certain support from prominent authorities. This procedure is in stark contrast to the substantial evidence rule which would have required the agency to factually set forth the basis for

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[15] Despite this clear legislative history, the Court of Appeals relies on one isolated word used in the Senate Report as evidence that substantive authority was intended (A 18). The Committee's reference to the single word "enforce," must be read in the context of the entire Senate Report as well as the House proceedings.

its decision.[16] The lower court recognized (A 22) that the decision of this Court in *Citizens to Preserve Overton Park* v. *Volpe*, 401 U.S. 402, 414 (1971) indicates that the substantial evidence rule was to be applied to all rule-making proceedings under 5 U.S.C. §553. However, the Court of Appeals held that a footnote to the decision of this Court in *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. at 622 n. 19, involved a retreat from the position taken in *Overton Park*.

It is respectfully submitted that this Court should resolve this issue as to the appropriate scope of review for all substantive agency action, presented to this Court for the first time.

II.

Section 503(b)(1)(B) of the Act sets forth specific and detailed requirements as to products which require a prescription under the statute. In the instant case, the agency

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[16] The distinction is very clearly set forth in the instant case with respect to the question of whether or not the products are drugs. In a related proceeding, *National Nutritional Foods Association* v. *Food and Drug Administration*, 504 F.2d 761 (2d Cir. 1974), the Second Circuit invalidated the same agency's attempt to classify as drugs all vitamins above a certain quantity level. Despite the fact that vitamins A and D, at issue herein, were also involved in that case, the Court of Appeals in the instant case nevertheless remanded for further proceedings on this issue in part because of the possibility that the narrower arbitrary and capricious standard in the instant case might yield a different result (A 25). Judge Lumbard's concurring opinion herein did recognize that the substantial evidence rule should be applicable for all substantive agency action, but felt that the District Court decision would have reached the same result even if it had applied the substantial evidence rule. As noted above, however, the comments received by the agency herein could not be considered substantial evidence and the majority opinion properly recognized that the agency action could not be affirmed on a substantial evidence basis (A 21).

prescription requirement was not based on a consideration of the intrinsic properties of the products in question. Instead, it was imposed on the theory that consumers might take too much of even safe quantities of vitamins A and D, thereby exposing themselves to a risk of potential toxicity at unspecified levels. This approach is not covered or contemplated by the prescription statute and is therefore in excess of the agency's authority under the Act.

Under the express statutory language, there are two requirements for the application of the prescription statute. First, a drug must be toxic or have other potentiality for harmful effect. Second, as a result of the above, the product must be "not safe for use *except* under the supervision of a practitioner licensed by law to administer such a drug." As noted earlier, Congress, in enacting the prescription statute, was very much concerned that the agency might remove safe products from the market.[17] As a result, a specific and precise standard was incorporated in the statute limiting prescription status to products which could not be used safely *except* under medical supervision. Under the Court of Appeals ruling, however, every drug could be subjected to prescription requirements simply because of the well known fact that they could be dangerous, if abused. The Congressional effort to preserve low cost over-the-counter drug products is therefore defeated.

If a product can be used safely with adequate directions for use, as contemplated and required by the statute under §502(f) [21 U.S.C. §352(f)], the prescription statute does not and was never intended to apply. Its purpose is not to establish "an obstacle to the swallowing of toxic amounts"

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[17] See Congressional debates cited *supra* at n. 14.

(B-12), but to assure that drugs requiring supervision be available only on a prescription basis. The statutory remedy for preventing excessive intake of drugs is specifically set forth in §502(f)(2) [21 U.S.C. §352(f)(2)] by which appropriate cautionary labeling is required in this respect.

Since the prescription limitations on vitamins A and D were not designed to meet the requirements of or to achieve the purpose of the prescription statute, it is respectfully submitted that *certiorari* should be granted to review this novel application of the prescription statute which threatens the entire structure of the over-the-counter drug market.

CONCLUSION

For the foregoing reasons, this petition for a writ of *certiorari* should be granted.

Respectfully submitted,

MILTON A. BASS
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Counsel for Petitioners

APPENDICES

APPENDIX A

Opinion of USCA-2d Circuit
National Nutritional Foods Association

UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

No. 228—September Term, 1974.

(Argued October 30, 1974 Decided February 3, 1975.)

Docket No. 74-1738

THE NATIONAL NUTRITIONAL FOODS ASSOCIATION and SOLGAR CO., INC.,

Plaintiffs-Appellants,

—against—

CASPER W. WEINBERGER, Secretary of Health Education and Welfare and ALEXANDER M. SCHMIDT, Commissioner of Food and Drugs,

Defendants-Appellees.

Before:

LUMBARD, WATERMAN and MANSFIELD,

Circuit Judges.

Appeal from an order of the United States District Court for the Southern District of New York, Marvin E. Frankel, *Judge*, vacating a notice of deposition by plaintiffs, manufacturers of Vitamins A and D, and granting summary judgment dismissing plaintiffs' complaint, which sought declaratory and injunctive relief against regulations promulgated by the Food and Drug Administration classifying those vitamins in excess of certain potencies per dosage as "drugs" under 21 U.S.C. §321(g)(1) and

further as "prescription drugs" under 21 U.S.C. §353(b)(1)(B).

Remanded for further proceedings, including a determination of the basis for, and legality of, the Commissioner's conclusions that dosage levels of Vitamins A and D in the amounts specified are "drugs" within the meaning of the Act.

MILTON A. BASS, Esq., New York, N.Y. (Bass & Ullman, New York, N.Y., of counsel), *for Appellants.*

NAOMI REICE BUCHWALD, Assistant United States Attorney (Paul J. Curran, United States Attorney for the Southern District of New York, Gerald A. Rosenberg, Assistant United States Attorney, New York, N.Y., of counsel), *for Appellees.*

KIRKPATRICK W. DILLING, Esq. and DENNIS M. GRONEK, Esq., Chicago, Ill. (Diana J. Dilling, Attorney, Chicago, Ill., of counsel), *for Amicus Curiae National Health Federation.*

MANSFIELD, *Circuit Judge:*

This appeal by producers and vendors of vitamin preparations arises out of their unsuccessful attempt in the Southern District of New York to challenge regulations promulgated by the United States Food and Drug Administration ("FDA" herein) pursuant to §701(a) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§301, et seq. (the "Act" herein), which classify as "prescription drugs" all preparations of Vitamin A containing more than 10,000 IU (international units) per dosage form and

of Vitamin D containing more than 400 IU per dosage form.[1] In the district court appellants sought declaratory and injunctive relief against the regulations, claiming that the FDA has no power to issue binding regulations under §701(a), that the vitamin preparations at issue are foods and were improperly classified as prescription drugs under the Act, that plaintiffs were entitled to a *de novo* trial in the district court of factual issues going to the basis of the regulations and that the FDA's action in promulgating them was unsupported by substantial evidence. Appellants further contended that the "whole record" of the agency's action was not before the district court, and sought to depose the Commissioner of Food and Drugs ("Commissioner" herein). The district court, Marvin E. Frankel, *Judge*, vacated the notice of deposition and granted summary judgment dismissing the complaint.

Purporting to act under the general rule-making power vested in the Secretary of Health, Education and Welfare ("HEW" herein) by §701(a) of the Act, 21 U.S.C. §371(a), which authorizes him "to promulgate regulations for the efficient enforcement of this Act," the Commissioner, to whom this rule-making authority is delegated, 21 C.F.R. 2.120(a)(1), followed the notice-and-comment procedure outlined by §4(c) of the Administrative Procedure Act,[2] 5 U.S.C. §553(c), in promulgating the challenged regulations. First he published a statement in the Federal Register, 37 Fed. Reg. 26618, on December 14, 1972, giving notice of his proposal to adopt regulations which would require that, pursuant to the "prescription drug" law,

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1 Prior to plaintiffs' suit in the district court a petition for review of the FDA promulgation was dismissed by us for lack of jurisdiction. See *Citizens for Truth in Nutrition* v. *FDA*, Dkt. No. 73-2826 (2d Cir. Mar. 4, 1974).

2 See p. 1612, *infra*.

§503(b)(1) of the Act, 21 U.S.C. §353(b),[3] Vitamins A and D in dosage units in excess of 10,000 IU and 400 IU, respectively ("higher dosage forms" herein) be restricted to prescription sale and deemed misbranded unless the label of the container in which they were sold or dispensed bore appropriate disclosure and warnings.

The Commissioner's initial statement advised that, according to medical literature, the ingestion of large dosages of Vitamins A and D over long periods could have serious toxic effects and that these vitamins were available over the counter in dosage forms many times the daily allowance recommended and published by the Food and Nutrition Board of the National Academy of Sciences—National Research Council ("NAS/NRC" herein). According to the Commissioner's statement the excess dosage forms were the subject of widespread promotion to the public for prophylaxis and treatment of a variety of diseases and disorders. The American Academy of Pediatrics had published a statement warning physicians regarding the va-

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3 "(b)(1) A drug intended for use by man which—

"(A) is a habit-forming drug to which section 352(d) of this title applies; or

"(B) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

"(C) is limited by an approved application under section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such drug,

shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale."

rious forms of toxicity that could result from intake of the large amounts of Vitamin A being recommended by vendors to the public in the press, on radio and on TV. Many types of serious adverse effects from ingestion of excessive amounts of Vitamins A and D were listed, including some that resulted in death. The recommended daily allowance ("RDA" herein) published by the Food and Nutrition Board of the NAS/NRC as between 4,500 and 5,000 IU of Vitamin A for older children and adults, 6,000 IU during pregnancy and 8,000 IU during lactation. For Vitamin D preparations the RDA was 400 IU for all age groups. The Commissioner placed on public view an extensive bibliography of the medical literature employed by the FDA in formulating its proposed regulations. The Commissioner's statement invited interested persons to file with the HEW within 60 days any written comments they might desire to submit with respect to the proposals, together with memoranda and briefs, all of which would be available for public inspection.

Over, 2,500 written comments were submitted by a wide cross-section of the public, including consumers, physicians, nurses, pharmacists, pharmaceutical manufacturers, health food store operators. Various organized consumer and other groups, including the Academy of Pediatrics, American Medical Association, and the Pharmaceutical Manufacturers Association also responded. Both plaintiffs in this case submitted extensive comments opposing the regulations. According to the Commissioner, the comments fell into three general categories: (1) Those who viewed the proposed regulations as suitable. This group included the American Medical Association, the American Academy of Pediatrics, various consumer groups, physicians and others; (2) Those who agreed that vitamins could be toxic, but at higher levels than those proposed by the Commissioner. In this group were the majority of the

drug manufacturers and trade associations plus some consumers; and (3) Those who disagreed with the proposals entirely, taking the view that such vitamin preparations are food and that consumption of desired quantities is an individual right. These comments came mostly from consumers and health food establishments.

In a report published in the Federal Register on August 2, 1973, 38 Fed. Reg. 20723, the Commissioner summarized the comments received by the FDA, concluded that the proposed regulations were in the public interest, and ordered that they become effective on October 1, 1973. In response to contentions that Vitamins A and D were foods rather than drugs, and thus not subject to regulation as "prescription drugs," the Commissioner referred to orders which he had published on January 19, 1973, promulgating as regulations §§80.1, 125.1 and 125.3 (21 C.F.R. §§80.1, 125.1 and 125.3).[4] He concluded that vita-

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4 21 C.F.R. §80.1(f)(1) sets forth Recommended Daily Allowances for many vitamins and minerals, including Vitamins A and D as follows:

U.S. GOVERNMENT RECOMMENDED DAILY ALLOWANCES (U.S. RDA's) AND PERMISSIBLE COMPOSITIONAL RANGES FOR DIETARY SUPPLEMENTS OF VITAMINS AND MINERALS

	Unit of Measurement	Children under 4 years of age[1]—U.S. RDA		Adults and children 4 or more years of age—U.S. RDA		Pregnant or lactating women—U.S. RDA	
		Lower Limit	Upper Limit	Lower Limit	Upper Limit	Lower Limit	Upper Limit
Vitamins							
Mandatory							
Vitamin A	International Units	1,250	2,500	2,500	5,000	5,000	8,000
Vitamin D[2]	do	200	400	400		400	400
Vitamin E	do	5	10	15	30	30	60
Vitamin C	Milligrams	20	40	60	60	60	120
Folic acid[3]	do	0.1	0.2	0.3	0.4	0.4	0.8
Thiamine	do	0.35	0.70	1.05	0.75	1.50	2.25
Riboflavin	do	0.4	0.8	1.2	0.8	1.7	2.6
Niacin	do	4.5	9.0	13.5	10.0	20.0	30.0
Vitamin B_6	do	0.35	0.70	1.05	1.00	2.00	3.00
Vitamin B_{12}	Micrograms	1.5	3.0	4.5	3.0	6.0	9.0
Optional					200	400	400
Vitamin D	International Units						
Biotin[3]	Milligrams	0.075	0.150	0.225	0.150	0.300	0.450
Pantothenic acid	do	2.5	5.0	7.5	5.0	10.0	15.0
Oral Mandatory							
Calcium	Grams	0.125	0.800	1.200	0.125	1.000	1.500
Phosphorus[4]	Do	0.125	0.800	1.200	0.125	1.000	1.500
Iodine	Micrograms	35	70	105	75	150	225
Iron	Milligrams	5	10	15	9	18	27
Magnesium	Do	40	200	300	100	400	600
Optional							
Phosphorus[4]	Grams					0.125	1.300
Copper	Milligrams	0.5	1.0	1.5	1.0	2.0	3.0
Zinc	Do	4.0	8.0	12.0	7.5	15.0	22.5

[1] When labeled for use by infants, a dietary supplement shall contain not less than the lower limit designated for a nutrient in this column nor more than 100% of the infant U.S. RDA for a nutrient as prescribed in §125.1(b) except that the level of biotin, when used, shall be 0.05 mg per daily recommended quantity.
[2] Optional for adults and children 4 or more years of age.
[3] Optional for liquid products.
[4] Lower limit may be 0.05 milligram until December 31, 1978.
[5] Optional for pregnant or lactating women. When present, the quantity of phosphorus may be no greater than the quantity of calcium.

mins in daily amounts between the upper and lower limits specified in §80.1 (i.e., 1,250 to 8,000 IU of Vitamin A and 200 to 400 IU of Vitamin D) were adequate for all nutritional needs of normal individuals and that nutrients at these levels could be considered as dietary supplements or foods for special dietary use. With respect to the higher level dosages, which were to be dispensed only upon prescription, however, he stated:

> "No evidence was submitted in the comments to establish a food or nutritional use of vitamin A or vitamin D at higher levels, except for a limited number of persons with poor vitamin D absorption who need up to 1000 IU of this vitamin for nutritional purposes under medical supervision. With that one exception, which is recognized in the revised regulation, intake of vitamins at levels exceeding the upper limits as specified in §80.1 are therefore appropriate only for therapeutic purposes and thus are properly classed as drugs."

On August 6, 1973, plaintiffs brought suit in the Southern District of New York seeking declaratory and injunctive relief that would prevent enforcement of the proposed regulations. In September 1973 Judge Frankel denied a motion for preliminary injunctive relief in an opinion at 366 F.Supp. 1341 (S.D.N.Y. 1973), which we affirmed, 491 F.2d 845 (2d Cir. 1973). On October 1, 1973, the regulations went into effect. In a further opinion dated April 5, 1974, published at 376 F. Supp. 142 (S.D.N.Y. 1974), Judge Frankel granted defendant's motion for summary judgment dismissing the complaint and upheld the regulations as having been promulgated pursuant to the Commissioner's authority under the Act. He further held that plaintiffs were not entitled to a *de novo* trial, preceded by discovery, to test the regulations, since the rule-making procedure

followed by the FDA, which resulted in voluminous comments, was adequate and the regulations were not irrational, arbitrary or capricious, which he deemed to be the standard of review. From this decision plaintiffs appeal.

Discussion

Appellants have launched a multifaceted attack upon the challenged regulations and the district court's grant of summary judgment. They contend that the FDA has no authority to issue regulations having the binding effect of law, other than those regulations which must be issued under the adjudicatory hearing procedures provided by §701(e) of the Act, 21 U.S.C. §371(e).[5] They argue that

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5 "(e)(1) Any action for the issuance, amendment, or repeal of any regulation under section 341, 343(j), 344(a), 346, 351(b), or 352(d) or (h), of this title shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall make such order public. Except as provided in paragraph (2) of this subsection, the order shall become effective at such time as may be specified therein, but not prior to the day following the last day on which objections may be filed under such paragraph.

"(2) On or before the thirtieth day after the date on which an order entered under paragraph (1) of this subsection is made public, any person who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections. Until final action upon such objections is taken by the Secretary under paragraph (3) of this subsection, the filing of such objections shall operate to stay the effectiveness of those provisions of the order to which the objections are made. As soon as practicable after the time for filing objections has expired the Secretary shall publish a notice in the Federal Register specifying those parts of the order which have been stayed by the filing of objections and, if no objections have been filed, stating that fact.

"(3) As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing

regulations issued under §701(a), which does not provide for a hearing, at best represent merely administrative interpretations of the substantive statutory law, enforceable only on a case-by-case basis that would insure *de novo* adjudication of all issues by the district court. They further assert that, even assuming *arguendo* that the FDA had the power to promulgate binding regulations, the present ones are deficient because they are unsupported by substantial evidence and the record fails to contain adequate findings and a sufficient explanation of the basis and rationale of the FDA's action to enable a reviewing court to determine whether the FDA acted within the scope of its statutory authority and on the basis of supporting evidence. They argue that the district court improperly used the "arbitrary, capricious" rather than the "substantial evidence" standard of review but that even the former could not be met here, in view of the inadequacy of the record, which fails adequately to demonstrate the basis of the Commissioner's action.

If this case had been one governed by hearing requirements like those in §701(e) or if the district court had held a *de novo trial*, appellants argue, crucial factual issues would have been resolved in their favor. They allege that they would have demonstrated that Vitamins A and D

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for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person may be heard in person or by representative. As soon as practicable after completition of the hearing, the Secretary shall by order act upon such objections and make such order public. Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based. The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions."

at the dosage levels specified in the regulations are not "drugs" as that term is defined in §201(g) of the Act, 21 U.S.C. §321(g),[6] because they were not intended for use in the treatment or prevention of disease but as dietary supplements, and that they could not lawfully be classified as "prescription drugs" under §503(b)(1)(B) of the Act, 21 U.S.C. §353(b)(1)(B), since the products are not toxic at the levels established by the regulations and are not inherently unsafe when used without prescription in a rational manner, but can become unsafe only when misused or used irrationally. The effect of the action of the FDA and of the district court, say appellants, is to withdraw a food from the market without a hearing and without findings, contrary to Congress' intent in enacting the prescription drug statute.

The FDA's Rule-Making Authority

Resolution of the issues raised by appellants requires an analysis of the FDA's rule-making power and of the federal court's role in reviewing the exercise of that power. As enacted in 1938 §701 of the Food and Drug Act, 21 U.S.C. §371, contained two grants of authority to the FDA to promulgate regulations. Section 701(a) broadly grants:

> "(a) The authority to promulgate regulations for the efficient enforcement of this chapter, except as

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6 "(g)(1) The term 'drug' means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement of any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clauses (A), (B), or (C) of this paragraph; but does not include devices or their components, parts, or accessories."

otherwise provided in this section, is vested in the Secretary."

No conditions were expressly imposed upon this expansive grant of authority. A few paragraphs thereafter, on the other hand, Congress prescribed in §§701(e) and (f) an elaborate procedure that must be followed by the FDA in promulgating regulations with respect to certain specifically enumerated subjects (e.g., standards of identity, 21 U.S.C. §341, branding of food for special dietary uses, 21 U.S.C. §343(j), distribution of potentially contaminated foods, 21 U.S.C. §344(a)), including notice, comments by interested parties, promulgation of proposed rules, filing of objections, a public evidentiary hearing if requested by a "party adversely affected," and a court of appeals review, 21 U.S.C. §371(e), (f).

Congress did not expressly spell out the authoritative effect that should be given to regulations promulgated under §§701(a) and 701(e).[7] This naturally leads one to wonder, in view of the care with which Congress spelled out the elaborate §701(e) procedure, whether it intended any limits on the apparently expansive delegation of rulemaking power granted by §701(a), and specifically whether (as appellants urge) the latter was meant merely to grant authority to issue interpretive, non-binding advisory opinions with respect to matters of lesser importance than those promulgated here, which serve the rather important function of defining the status of a product as a food or drug and restricting certain products to prescription sale as drugs.

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7 The legislative history does confirm that §701(e) regulations "are not merely interpretive. They have the force of law and must be observed." H. Rep. No. 2139, 75th Cong., 3d Sess. (1938), p. 12. However, there is no statement indicating that §701(a) regulations were to have similar effect.

The FDA, like most federal agencies, does have power to issue "interpretive" regulations. Agency interpretations of substantive statutory law have been viewed as "not controlling upon the Courts by reason of their authority," *Skidmore* v. *Swift & Co.*, 323 U.S. 134, 140 (1944), but merely as "a body of experience and informed judgment to which the courts and litigants may properly resort for guidance," *id.* Appellants urge upon us the view that all regulations issued pursuant to §701(a) are advisory only, and are subject to *de novo* challenge in court enforcement proceedings. This position has frequently been taken by members of the drug industry:

> "Interpretive regulations . . . issued pursuant to section 701(a) consist of FDA opinions of the meanings of various sections of the Act, and opinions as to the impact of those sections on particular fact situations. They have advisory effect only. That is, they tell private parties what the FDA position will be in an enforcement proceeding. But in that proceeding, the court must consider, on a full evidentiary showing, whether the particular conduct challenged by the FDA pursuant to its announced enforcement policy is a violation of the Act." Munsey, Survey of Current Legal Problems in the Drug Area, 23 Food, Drug and Cosmetic L.J. 449, 454 (1968).

See also Cody, Authoritative Effect of FDA Regulations, 24 Food, Drug and Cosmetic L.J. 195, 196 (1969).

A court may well consider it within its power to review the legality of some types of regulations which seek at length to flesh out the terms of a broad statute, especially when the regulations themselves are rather imprecise. In such cases a court in an enforcement proceeding will in any event be forced to develop a considerable factual

record to determine whether there has been a violation of the regulation. But, as Judge Frankel observed, attempts to draw a hard and fast line between "interpretive" and "substantive" regulations have been rather unrewarding. The line of demarcation between the two is often far from clear. Faced with the argument advanced here by appellants we stated in *Toilet Goods Ass'n* v. *Gardner,* 360 F.2d 677, 686 (2d Cir. 1966), *aff'd.,* 387 U.S. 167 (1967), "Neither do we think anything is to be gained by an attempt at comprehensive review of the decisions; the many cases in this area are not truly reconcilable. . . ." We have come to recognize that, if the administrative process is to be practically effective, specific regulations promulgated pursuant to a general statutory delegation of authority must be treated as authoritative, whether labelled "substantive" or "interpretive," especially in areas where the agency possesses expertise not shared by the courts. In that event its views are unlikely to be disturbed by the court in an enforcement proceeding. See, e.g., *Abbott Laboratories* v. *Gardner,* 387 U.S. 136, 151-52 (1967); *CIBA-GEIGY Corp.* v. *Richardson,* 446 F.2d 466, 468 (2d Cir. 1971). Where once we may have demanded proof of specific delegation of legislative authority to an agency purporting to promulgate substantive rules we have learned from experience to accept a general delegation as sufficient in certain areas of expertise.

Whatever doubts might have been entertained regarding the FDA's power under §701(a) to promulgate binding regulations were dispelled by the Supreme Court's recent decisions in *Weinberger* v. *Hynson, Westcott & Dunning, Inc.,* 412 U.S. 609 (1973), and its companion cases, *Ciba Corp.* v. *Weinberger,* 412 U.S. 640 (1973); *Weinberger* v. *Bentex Pharmaceuticals, Inc.,* 412 U.S. 645 (1973); *USV Pharmaceutical Corp.* v. *Weinberger,* 412

U.S. 655 (1973). Those decisions interpreted §701(a) as giving FDA the power to promulgate substantive regulations having the binding force of law rather than mere "interpretive" statements enforceable only on a case-by-case basis through plenary suits against those refusing to comply. The Court upheld the power of the FDA under §701(a) to promulgate binding regulations which (1) defined the standards of evidence to be met by drug manufacturers called upon to demonstrate the efficacy of their products in new drug applications, and (2) permitted the dismissal without a hearing (i.e., by summary judgment) of an application failing to meet these standards. The Court further approved administrative determination by the FDA of whether a product was a "new drug" within the meaning of the Act. In sanctioning the equivalent of an administrative summary judgment procedure Justice Douglas, speaking for the Court, stated:

> "If FDA were required automatically to hold a hearing for each product whose efficacy was questioned by the NAS-NRC study, even though many hearings would be an exercise in futility, we have no doubt that it could not fulfill its statutory mandate to remove from the market all those drugs that do not meet the effectiveness requirements of the Act." 412 U.S. at 621.

The same pragmatic view was taken with respect to the FDA's power to determine administratively the "new drug" status of a product, the Court stating that the FDA could not "administer the act intelligently and rationally unless it has authority to determine what drugs are 'new drugs' ", 412 U.S. at 624, and continuing with the observation:

> "To require separate judicial proceedings to be brought against each [drug manufacturer], as if each were the owner of a Black Acre being condemned, would be to

create delay where in the interests of public health there should be prompt action. A single administrative proceeding in which each manufacturer may be heard is constitutionally permissible measured by the requirements of procedural due process." 412 U.S. at 625.

In *Ciba Corp.* v. *Weinberger,* 412 U.S. 640 (1973), the FDA's power to determine "new drug status" in definitive administrative proceedings, as distinguished from the power to seek such determinations in case-by-case enforcement proceedings, was established beyond any serious question. The Court held that a district court may properly defer to the FDA's primary jurisdiction, and observed that in providing the FDA with a "second line of defense" —injunction proceedings and seizure actions—"the Act does not create a dual system of control—one administrative, the other judicial," 412 U.S. at 644. Finally the Court in *Bentex Pharmaceuticals, supra,* recognized the FDA's power to promulgate binding regulations not only for pragmatic reasons but on the ground that the FDA, by reason of its expertise, was better equipped to make such determinations than a court which is "without chemical or medical background," 412 U.S. at 652-53.

These decisions clearly point to the conclusion that the FDA may promulgate regulations of the type challenged here. Congress' establishment of a specific (and elaborate) procedure in §701(e) authorizing the FDA to promulgate regulations in certain fields was in addition to and not in derogation of the general rule-making power granted to the FDA by §701(a). Under the latter section, furthermore, the FDA may follow streamlined procedures designed to avoid the endless delays that have tended to

paralyze adjudicatory hearings and render them ineffective as a means of utilizing agency expertise.[8]

Our attention has not been directed to anything in the legislative history of §§701(a) and (e) that militates against these conclusions. On the contrary, over the last decade rule-making has been increasingly substituted for adjudication as a regulatory technique, with the support and encouragement of courts, at least where the regulation involves specialized scientific knowledge. See *NLRB* v. *Wyman-Gordon Co.*, 394 U.S. 759 (1968); *Mourning* v. *Family Publications Serv., Inc.*, 411 U.S. 356 (1973); *National Petroleum Refiners Assn.* v. *FTC*, 482 F.2d 672 (D.C. Cir. 1973), *cert. denied*, 415 U.S. 951 (1974); *Anaconda Co.* v. *Ruckelshaus*, 482 F.2d 1301 (10th Cir. 1973); *United States* v. *Florida East Coast Railway*, 410 U.S. 224 (1973). Where the objective is essentially legislative, i.e., to establish rules or principles by which an entire industry may be governed, the case-by-case adversary proceeding, in which the agency confronts a single alleged offender selected for suit with respect to a specific factual situation, has frequently proved to be an unsuitable method of enforcing the law, since it often resolves narrow issues of importance only to the immediate adversaries rather

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8 The proceedings under §701(e) at issue in *NNFA* v. *FDA*, for example, were begun in 1962, 504 F.2d at 768. The notorious proceeding which established standards of identity for peanut butter lasted more than 10 years. See Hamilton, *Rulemaking on a Record by the Food and Drug Administration*, 50 Texas L. Rev. 1132, 1142-45 (1972).

Appellants contend that the use of a notice and comment procedure in this case was wholly gratuitous, and that the FDA can use procedures under §701(a) so "streamlined" that objectants have no procedural rights. This is clearly not the case. When adopting a rule that purports to have the force of law, the agency is bound by the procedural requirements of §4 of the Administrative Procedure Act, 5 U.S.C. §553. Whatever the term "interpretive" may mean in other contexts, it seems apparent that the exemption from §4 requirements provided in 5 U.S.C. §553(b)(3)(A) for "interpretive rules" refers only to rules not intended to have the force of law.

than broad questions of interest to the industry or the public. The rulemaking proceeding, on the other hand, provides the agency with an opportunity first to receive a wide spectrum of views proffered by all segments affected by the proposed rule (e.g., manufacturers, vendors, doctors, consumers) and then in a legislative fashion to consider and choose from several alternatives or options rather than limit its decisions to narrow issues controlling a particular case. Furthermore, once binding regulations are promulgated, the industry and public are put on notice and may be guided accordingly rather than speculate as to the outcome of a seizure or enforcement suit. See Shapiro, The Choice of Rulemaking or Adjudication in the Development of Administrative Policy," 78 Harv. L. Rev. 921 (1965).

Whether the FDA's Rule-Making Power under §701(a) Extends to "Prescription Drugs" as Defined in §503(b)(1) of the Act

Appellants contend that, regardless what the FDA's rule-making power under §701(a) may be with respect to other matters, the legislative history of the "prescription drug" statute, §503(b)(1) of the Act, 21 U.S.C. §353(b)(1), demonstrates that Congress intended to deny the agency the power to make binding rules specifying those products that would require a prescription. Congress, they argue, intended that the FDA must seek resolution of that issue through case-by-case enforcement proceedings. We disagree.

The legislative history of the prescription drug statute, which was enacted by Congress in 1951 as the Durham-Humphrey Amendment to the Act, sheds no clear light on the question of what rule-making authority Congress assumed or intended that the FDA would have in deciding

what drugs must be sold only on prescription. Differing versions of the amendment, as they appeared first in the House and later in the Senate, delegated varying degrees of power to the FDA and were the subject of differing interpretations by members of Congress. Delving into the House and Senate Committee Reports and statements by members of Congress on the floor, one can find expressions construing the agency's power as interpretive only, with the issue of whether any product was a prescription drug to be determined by the court in enforcement proceedings.[9] On the other hand, the Senate Report issued in support of the legislation as it was finally enacted, which should be deemed more authoritative than statements by individual Congressmen at earlier stages before amendments were made, see *Zuber* v. *Allen*, 396 U.S. 168, 186 (1969); *United States* v. *O'Brien*, 391 U.S. 367, 385 (1968), indicates that Congress intended the FDA to exercise its rule-making powers under §701(a) in order to "enforce" the statute.[10] Were we required to decide the question

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9 The report of the House minority committee whose position generally prevailed in that chamber stated an objection to the prescription drug provisions since they

> "would make basic changes in the method of determining which drugs are dangerous and may be sold only on prescription, and which drugs are safe and may be sold over the counter. We think the present method, which leaves this determination to the courts, should be left unchanged except that a proper standard to be applied in determining whether a drug is dangerous should be incorporated in the statute." H. Rep. No. 700, 82d Cong., 1st Sess. (1951), p. 28.

The minority further suggested that providing the Federal Security Administrator with administrative power to list "prescription" drugs was "a dangerous delegation of authority" which would "add to the present difficulties by increased bureaucratic regulation." *Id.*

10 "In order to give this general definition a more precise meaning so that it may be applied with greater uniformity by the drug trade the Administrator can exercise the authority he has under section 701(a) of the Federal Food, Drug, and Cosmetic Act to issue inter-

solely on the legislative history we would lean to the view that Congress expected the FDA, particularly in view of its expertise, to promulgate from time to time *binding* interpretations of the standards set forth in the prescription drug statute, subject to judicial review, rather than leave the decision to the courts, which lack the medical and scientific knowledge essential to such decisions. Whatever doubts we might have had on the question, however, have been resolved by the Supreme Court's interpretation of the FDA's rule-making power in *Hynson* and its companion cases. Surely an agency which possesses the power to determine administratively what products are "new drugs" has the authority to decide what products are "prescription drugs."

The Adequacy of the Procedures Followed by the FDA

Since §701(a) of the Act, pursuant to which the challenged regulations were adopted, does not require an evidentiary hearing, the FDA was authorized to use the "no-

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pretative regulations. It is to be understood that the inclusion of the statutory definition does not, of course, in any way derogate from the Administrator's authority to interpret and enforce the definition through the issuance of any regulations necessary or appropriate to protect the public from indiscriminate dispensing of drugs over the counter when they may be unsafe for use without the supervision of a practitioner licensed by law to administer such drugs." S. Rep. No. 946, 82d Cong., 1st Sess. (1951), pp. 4-5.

"Furthermore, in determining whether a drug is safe for use without medical supervision, there must be taken into consideration not only the drug's toxicity, but also other potentialities for harmful effect, the method by which it is used, and the collateral measures necessary to its safe use. The broad language of the definition contained in this subparagraph is intended to comprehend all drugs that in fact should be administered under medical supervision in order to insure their safe use. Such difficult borderline cases as may arise under this definition can be dealt with under the interpretative and rule-making power provided for in section 701(a) of the act." *Id.* at 8-9.

tice and comment" procedure prescribed by §4 of the Administrative Procedure Act, 5 U.S.C. §553(c), which provides:

> "(c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose. When rules are required by statute to be made on the record after opportunity for an agency hearing, sections 556 and 557 of this title apply instead of this subsection."

This procedure has been generally recognized as adequate for the purpose of airing issues, evidence, and relevant factors to be considered by an agency in determining whether a rule is to be promulgated and, if so, its terms. See, e.g., *National Petroleum Refiners Assn.* v. *FTC*, 482 F.2d 672 (D.C. Cir. 1973), *cert. denied*, 415 U.S. 951 (1974).

Before adopting the regulations the FDA scrupulously followed the procedure prescribed by §4. Appellants and all others concerned were given ample notice of the proposed action and an opportunity to submit documents, data and arguments. Many groups including appellants took advantage of this opportunity and submitted extensive and detailed comments containing medical and scientific data, analyses, criticism, suggested revisions and alternative proposals. These extensive submissions were collated by the FDA in some 46 folders. Appellants not only set forth their own views and data in detail but were permitted to examine the opposing comments and data submitted by others and to examine and criticize the medical literature

relied upon by the FDA. It is undisputed that the FDA gave consideration to this mass of information in deciding whether to promulgate its proposed regulations. Since the decision did not turn on precise factual issues or on the credibility of witnesses but represented a judgment based upon consideration of relevant medical and scientific data, we doubt that a trial-type adversary hearing would have shed any further light on the question of whether restriction of the sale of higher dosage levels of Vitamins A and D to prescription sale would be in the public interest. The question was one to be resolved on the basis of a general appraisal of the risk of toxicity. It is conceded that even with the regulations in effect a purchaser of preparations containing less than the IU content required for prescription could suffer the effects of excessive ingestion by consuming a larger number of the less potent dosage forms. However, the Commissioner believed from experience that the regulations would lessen the risk of excessive intake that would be presented by the availability across the counter of higher potencies in single dosage units.

Appellants contend that the district court erred in applying the "arbitrary, capricious" rather than the "substantial evidence" standard prescribed by 5 U.S.C. §706 (2)(E). We disagree. Section 706(2)(E) is restricted to agency action in which an evidentiary hearing is required. Since no such hearing was required in the present case the appropriate standard for review of a regulation promulgated pursuant to the "notice and comment" procedure has been recognized to be that specified by 5 U.S.C. §706 (2)(A), which authorizes a reviewing court to hold unlawful and set aside agency action, findings and conclusions found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." See *National Nutritional Foods Assn.* v. *FDA*, 504 F.2d 761, 773 n.8 (2d Cir. 1974); *Consumer Union of United States*

v. *Consumer Product Safety Commission*, 491 F.2d 810 (2d Cir. 1974). Although the Supreme Court in *Citizens to Preserve Overton Park* v. *Volpe*, 401 U.S. 402 (1971), referred to the substantial evidence test in connection with rule-making proceedings under 5 U.S.C. §553, it later made clear in *Hynson* that this standard applies only to proceedings which are the subject of hearing provisions provided by 5 U.S.C. §§556 and 557 or to review of the record of an agency hearing provided by statute and that it did not apply to regulations promulgated by the FDA pursuant to §701(a) of the Food, Drug and Cosmetic Act. See *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. at 622 n.19. See also *Camp* v. *Pitts*, 411 U.S. 138, 140-41 (1973) (per curiam).

The requirement in 5 U.S.C. §553(c) that an agency promulgating rules pursuant to the "notice and comment" procedure "incorporate in the rules a concise general statement of their basis and purpose" certainly does not require the agency to supply specific and detailed findings and conclusions of the kind customarily associated with formal proceedings, *Consumer Union of United States* v. *Consumer Product Safety Commission*, 491 F.2d at 812. But this provision does not lessen or excuse the agency's obligation to publish a statement of reasons that will be sufficiently detailed to permit judicial review, *Automotive Parts & Accessories Assn.* v. *Boyd*, 407 F.2d 330, 338 (D.C. Cir. 1968), and even under the "arbitrary, capricious" standard agency action will not be upheld where inadequacy of explanation frustrates review. *Camp* v. *Pitts*, 411 U.S. 138 (1973); *Citizens to Preserve Overton Park* v. *Volpe*, 401 U.S. 402 (1971). Indeed the very absence of a detailed record of the type that would be made if an evidentiary hearing were held makes it advisable for the agency, in lieu thereof, to provide a thorough and comprehensible statement of the reasons for its decision. Where

the agency's "finding is not sustainable on the administrative record made, the . . . decision must be vacated and the matter remanded to [the agency] for further consideration." *Camp* v. *Pitts*, 411 U.S. at 143; cf. *Kennecott Copper Corp.* v. *Environmental Protection Agency*, 462 F.2d 846, 850 (D.C. Cir. 1972) (remanding to the agency for explanation of the basis of its finding).[11]

A failure of the agency adequately to explain its actions is not a warrant to the district court to conduct a *de novo* evidentiary hearing, *Camp* v. *Pitts*, supra. "[T]he focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court." 411 U.S. at 142. Instead, the remedy under these circumstances is "to obtain from the agency, either through affidavits or testimony, such additional explanation of the reasons for the agency decision as may prove necessary." *Id.* at 143; cf. *Kennecott Copper Corp.* v. *EPA*, *supra*.

Applying the foregoing principles here, a serious question is raised as to whether the Commissioner, in concluding that the higher level dosage forms of Vitamins A and D are "drugs," acted "in accordance with law," as that phrase is used in 5 U.S.C. §706(2)(A). The question is posed by §201(g) of the Act, 21 U.S.C. §321(g), which defines a "drug" as an article recognized in the United States Pharmacopoeia or "intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease." Protection of the public health dictates that these definitions be construed liberally and that the FDA's determination be given considerable weight, *United States* v. *An Article of*

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11 Although we have stated that regulations may be supported not only by the record but by the FDA's "experience," see *Consumers Union of United States* v. *Consumer Product Safety Commission*, 491 F.2d 810 (2d Cir. 1974), the agency's experience, to the extent that it provides a *factual* basis for a regulation under attack, must be a matter of record in order to qualify for consideration by a reviewing court.

Drug—Bacto-Unidisk, 394 U.S. 784, 792, 798 (1968), provided it is not unreasonable, *Udall* v. *Tallman*, 380 U.S. 1, 16-18 (1965), and has some support in the record, *Camp* v. *Pitts*, *supra* at 143. Judge Frankel dismissed quickly the argument that Vitamins A and D were improperly classified as drugs, stating simply that "the products here are squarely within the literal language and evident meaning of the statute." However, since the district court's determination this court decided *National Nutrition Foods Assn.* v. *FDA*, 504 F.2d 761 (2d Cir. 1974) ("*NNFA* v. *FDA*" herein), which suggests that a greater inquiry by the district court is required. In that case, upon a petition to review FDA regulations fixing standards of identity and label statements for vitamin supplements sold as foods, which had been promulgated after an evidentiary hearing under §701(e)(3) of the Act, 21 U.S.C. §371(e)(3), we invalidated §125.1(h),[12] which provided that any product containing more than the upper limit of the U.S. RDA per serving or daily recommended quantity (apparently 8,000 IU of Vitamin A and 400 IU of Vitamin D) is a drug. Judge Friendly reasoned that, although vitamins may be listed in the U.S. Pharmacopoeia or official National Formulary, this fact was not relied upon by the parties or the FDA as the reason for classifying these potencies as drugs and it represented at best a *post hoc* rationaliza-

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12 "(h) Any product containing more than the upper limit of the U.S. RDA per serving (or, where appropriate, per daily recommended quantity) of a vitamin or mineral as specified in §80.1 (f)(1) of this chapter is a drug, except for conventional foods which contain naturally-occurring amounts in excess of these limits or which contain added amounts in excess of these limits pursuant to §1.8(e) of this chapter so that it is not nutritionally inferior to the food for which it substitutes and which it resembles, and except as provided for in a specific regulation for such special dietary foods as infant formulas or foods which are represented for use solely under medical supervision to meet nutritional requirements in specific medical conditions."

tion which would not suffice to validate the regulation, see *Burlington Truck Lines Inc.* v. *United States,* 371 U.S. 156, 168 (1962). He further concluded that the argument would in any event prove too much, since it would require that all vitamin preparations, including those of less strength, which were treated by the FDA as dietary supplements, be classified as drugs.

Since the record indicated that a significant number of persons, principally women taking oral contraceptives, used the higher dosage levels for nutritional purposes, Judge Friendly found that the record did not reveal sufficient evidence that such preparations were intended for therapeutic purposes to satisfy the "substantial evidence" standard, which controlled upon review of a regulation promulgated under §701(e), and that the evidence of therapeutic intent or use must consist of "more than demonstrated uselessness [of the higher level forms] as a food for most people."

Since the Commissioner, in determining the "drug" status of the higher dosage levels of Vitamins A and D in this proceeding, appeared to rely heavily on the same record and conclusions that formed the basis for the regulation challenged in *NNFA* v. *FDA,* appellants argue that the determination here must *a fortiori* be invalidated. We disagree. We are here dealing with regulations which (1) differ in material respects from §125.1(h), (2) were promulgated under a different statute, §701(a), and (3) are subject to a less stringent standard of review. We are not, however, in a position to determine whether application of the lesser standard of review would yield the same result as that reached with respect to §125.1(h), since we do not appear to have the Commissioner's complete reasoning behind his classification of the higher dosage levels as drugs. Nor does it appear that we have been furnished

with the entire record that formed the basis of the FDA's classification.

Upon adoption of the regulations the Commissioner stated that since there was no evidence that the higher dosage levels were used for nutritional purposes except for use of Vitamin D by a limited number of persons with poor Vitamin D absorption needing up to 1,000 IU daily, they "are therefore appropriate only for therapeutic purposes and thus properly classed as drugs." As Judge Friendly said, "demonstrated uselessness as a food for most people" would not automatically establish that the higher levels qualify as a "drug" within the definition in §201(g)(1). The statute requires a finding of intent that a product be used for therapeutic purposes, and the Commissioner made no such finding. However, in his earlier statement proposing the regulations here under review the Commissioner stated that "there is widespread promotion to the laity of excessive quantities of these vitamins for prophylaxis and treatment of a variety of diseases and disorders." This statement indicates that the Commissioner, upon promulgating the regulations, may not have fully stated his reasons for classifying the higher levels as drugs. It is conceivable, for instance, that the Commissioner had before him information demonstrating that the higher dosage forms were used almost exclusively for therapeutic purposes. Measuring intent on an objective basis, as it must be, he may have concluded that in view of the extremely small percentage used for nutritional purposes Vitamins A and D at higher dosage levels were intended for use in the "cure, mitigation, prevention or treatment of disease." In that case his action could hardly be arbitrary or capricious and the regulations could, consistently with *NNFA* v. *FDA*, be upheld.

Furthermore, there are several differences between the proceeding before the *NNFA* v. *FDA* court and that here.

As to Vitamin A there is a difference between the upper level encountered in *NNFA* v. *FDA* (more than 8,000 IU) and that before us (more than 10,000 IU). Moreover, the present regulations, unlike §125.1(h), specifically provide that one higher dosage form mentioned as being vended for nutritional purposes in *NNFA* v. *FDA,* i.e., Vitamin D up to 1,000 IU per dosage, may be used under medical supervision to meet nutritional requirements, provided it is so labelled. Unlike §125.1(h), which declared on the basis of general reasoning that a broad range of vitamins and minerals are "drugs" when vended in dosages exceeding their RDA's, the regulations here are directed specifically at two vitamins, A and D. This suggests that the Commissioner may have engaged in a more detailed and specific consideration of these vitamins than was apparent in the §125.1(h) proceeding. Finally, there appears to be evidence in the record, upon which the Commissioner may have relied, indicating that high potency vitamin products are labelled in such a way (e.g., "Take one a day or as *directed by a physician*") as to indicate a therapeutic use.

Since the foregoing differences may prove to be significant, invalidation of the regulations here under attack is not automatically mandated by our decision in *NNFA* v. *FDA*. The situation is substantially similar to that encountered in *Citizens to Preserve Overton Park* v. *Volpe,* 401 U.S. 402 (1971), and the remedy prescribed by the Supreme Court in that case appears to be appropriate here. Accordingly we remand the case to the district court with directions to conduct an *Overton*-type hearing (including such affidavits or testimony as to the Commissioner's reasoning as the court deems necessary) for the purpose of determining whether, upon the entire administrative record before the Commissioner, which the court should scrutinize, *Silva* v. *Lynn,* 482 F.2d 1282 (1st Cir.

1973), the Commissioner acted rationally in classifying the higher Vitamin A and D dosage levels as a "drug" within the meaning of §201(g) of the Act, 21 U.S.C. §321(g). If the district court concludes that the Commissioner acted rationally, the regulations may be upheld and the order granting summary judgment should stand. The Commissioner's action in requiring that the higher dosage levels be sold only upon prescription could in that event hardly be labelled arbitrary, capricious or contrary to law.

We reject petitioners' contention that because the higher dosage levels are not "inherently" unsafe but become unsafe only if used in violation of cautionary labelling they do not qualify as "prescription" drugs within the meaning of §503(b) of the Act, 21 U.S.C. §353(b). The broad language of §503(b)(1)(B)[13] permits consideration of the various factors surrounding the use of a particular drug in determining that it "is not safe for use except under the supervision of" a physician. There was ample evidence before the FDA that Vitamins A and D, when consumed in large quantities over a period of time, can be acutely toxic. It was reasonable for the Commissioner to recognize that the risks of toxicity are increased by over-the-counter availability of readily ingestible, high dosage forms, and therefore he could rationally conclude that these forms have a "potential harmful effect."

The appellants' arguments that the Commissioner's determination is irrational because high concentrations of Vitamins A and D also occur in natural foods, use of which is not restricted, and because the Commissioner's rationale would also require drugs like aspirin to be placed on a prescription basis, must also be rejected. Although some ordinary foods contain potent doses of Vitamins A and D,

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13 See fn. 3 *supra*.

there is no indication that these foods are consumed on the same regular basis as the easily ingestible pills. Indeed, the fact that many persons obtain significant quantities of these vitamins from ordinary foods increases the risks of toxicity from regular consumption of high dosage pill forms. Likewise, although consumption of aspirin in excessive quantities presents risks of toxicity, there is no evidence that aspirin is consumed on the same regular basis as vitamins. The FDA here was not confronted with a case in which there was the mere possibility that a drug would be occasionally misused, but one in which the actual way in which the product is apparently used on a normal basis by many persons presents serious risks of toxicity. The Commissioner's action in classifying the higher dosage forms as "prescription drugs" thus cannot be called irrational or arbitrary.[14]

If, however, the district court concludes on remand that the Commissioner's treatment of the higher dosage forms as "drugs" under the §201(g) definition, based on the record before the Commissioner, is irrational, then the order granting summary judgment must be vacated.

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14 Appellants urge the decision in *United States* v. *An Article of Drug—Decholin*, 264 F. Supp. 473 (E.D. Mich. 1967) as support for their position that the higher dosage form vitamins cannot be classified as prescription drugs. That case involved an effort by the Government to classify Decholin as a prescription drug because there was a possibility that if used in certain ways it could harm. The *Decholin* case is not in point however since there had been no proof at all of toxicity. Here, the appellants do not contest the findings of Vitamin A and D toxicity at least at very high levels. Moreover, in *Decholin* the court states:

> "[T]he Government all but concedes that if future unadvised laymen act as their predecessors have, the drug will not be responsible for any serious consequences. . . . [W]hile in theory Decholin may be harmful as an over-the-counter drug, in practice it is safe for use without a prescription." 264 F. Supp. at 478.

In our case, the Government takes just the reverse position—although higher dosage vitamin tablets may theoretically be safe if used as directed, they are in practice not safe for use without a prescription.

The case is remanded to the district court for further proceedings not inconsistent with the foregoing.

LUMBARD, *Circuit Judge* (concurring):

I am not as confident as my brothers that Congress intended the FDA to have substantive rule-making authority with respect to the prescription status of drugs. However, in light of the bare statutory language of section 701(a), 21 U.S.C. § 371(a), the lack of clear legislative history denying such power to the FDA, and recent judicial trends, see, e.g., *Mourning* v. *Family Publication Services, Inc.*, 411 U.S. 356 (1973); *National Petroleum Refiners Assn.* v. *FTC*, 482 F.2d 672 (D.C. Cir. 1973), *cert. denied*, 415 U.S. 951 (1974), there seems little doubt that these regulations would be upheld by the Supreme Court.

What motivates this brief concurring statement is my concern that substantive agency action receive adequate review in the courts. What Congress intended in 1938, when the FDA was created, is less than clear with respect to the exercise of substantive rule-making powers under such a provision as section 701(a). However, in light of the fact that the FDA did not choose to exercise such power for so many years after it was supposedly granted, it would be less than realistic to think that Congress gave such rule-making much thought when it passed the Administrative Procedure Act in 1946.[1] Consequently, the quality and nature of judicial review of such rule-making as occurred here is open to some speculation.

As Judge Mansfield points out, the Administrative Procedure Act provides that the proper scope of review here is whether the agency action was "arbitrary, capricious, an

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1 Another example of an agency recently deciding that a long-standing statute authorized the issuance of substantive rules is provided by *National Petroleum Refiners Assn.* v. *FTC*, supra.

abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). This is so despite the fact that Congress provided a different form of review—one which required the FDA's actions to be based on substantial evidence—when it specifically authorized the FDA to engage in substantive rule-making. *See* 21 U.S.C. § 371(e)-(f).

Courts have chosen to uphold ever more generously and liberally the exercise of substantive rule-making powers by administrative agencies. Consequently it seems to me only appropriate that when courts approve such broader powers, they give due consideration to whether analogous changes may be needed in judicial interpretation of the Administrative Procedure Act. In cases such as this, where an agency engages in substantive rule-making under the authority of a general rule-making authorization, the courts should interpret the phrase "arbitrary, capricious, [or] an abuse of discretion" so as to ensure that real judicial review of agency action is provided. A district judge should carefully examine the information that was before the agency to see if it gives adequate and substantive support to the agency's position.[2] While a court should not substitute its views for those of the agency, it should not think that the "arbitrary [or] capricious" standard is so loose that it must approve anything that an agency does so long as the agency's actions are not completely irrational. Indeed, in the area of substantive rule-making a court should not hesitate to overturn an agency's action if it is not fairly supported by the evidence before the agency. In essence I think that when an agency engages in substantive rule-making, it abuses its discretion (or acts arbitrarily

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2 Section 4 of the Administrative Procedure Act, 5 U.S.C. § 553, requires that an agency give "a concise general statement of [the] basis and purpose" of rules that it adopts. As Judge Mansfield notes, an agency has an obligation to publish a statement of reasons that is sufficiently detailed to permit judicial review. Opinion at 25.

or capriciously) if its actions are not supported by substantial evidence. Cf. 5 U.S.C. § 706(2)(E).

Although Judge Frankel applied the traditional "arbitrary [or] capricious" standard of review in this case, an examination of the language of his two opinions on these regulations suggests to me that he did conduct a review similar to what I espouse here. Indeed, at one point he states that he probably would have reached the same conclusion as the FDA did on a particular issue if he had initially been called to rule on it.

For these reasons, I concur.

APPENDIX B

Opinion in *National Nutritional Foods Association* v. *Weinberger* (Denying Motion for Preliminary Injunction) Officially Reported at 366 F.Supp. 1341 (SDNY, 1973)

MEMORANDUM

FRANKEL, District Judge.

On October 1, 1973, regulations of the Food and Drug Administration will become effective requiring that preparations of Vitamin A and Vitamin D in excess of 10,000 I.U. (international units) per dosage unit and 400 I.U. per dosage unit, respectively, shall be restricted to prescription sale and that such vitamins shall be labelled accordingly. The regulations read as follows:

21 C.F.R. § 3.94

"(a) Vitamin A is an essential nutrient for humans. It is widely recognized that large amounts of vitamin A can cause adverse effects, some of which are serious. The U.S. Recommended Daily Allowance (U.S. RDA) for vitamin A is 1500 International Units, (IU) for infants, 2500 IU for children under 4 years of age, 5000 IU for adults and children 4 or more years of age, and 8000 IU for pregnant or lactating women.

"(b) In view of the toxicity of excessive consumption of vitamin A, the Food and Drug Administration finds that, in order to protect the public health, oral preparations containing vitamin A in excess of 10,000 IU per dosage unit or recommended daily intake are drugs subject to section 503(b)(1) of the Federal Food, Drug,

and Cosmetic Act and shall be restricted to prescription sale. Such products will be regarded as misbranded if at any time prior to dispensing the following conditions are not met:

"(1) The label bears the legend, 'Caution: Federal law prohibits dispensing without a prescription'; and

"(2) The labeling bears full disclosure information as required by § 1.106(b)(3)(i) of this chapter, and especially appropriate warnings regarding vitamin A toxicity.

"(c) Preparations containing 10,000 or less IU of vitamin A per dosage unit will be regarded as misbranded if their recommended daily intake exceeds 10,000 IU."

21 C.F.R. § 3.95

"(a) Vitamin D is an essential nutrient for humans. It is widely recognized that vitamin D, when ingested daily in large amounts, is toxic. The U.S. Recommended Daily Allowance (U.S. RDA) for vitamin D is 400 International Units (IU).

"(b) In view of the toxicity of the excessive consumption of vitamin D, the Food and Drug Administration finds that, in order to protect the public health, oral preparations containing vitamin D in excess of 400 IU per dosage unit or recommended daily intake are drugs subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act and shall be restricted to prescription sale. Such products will be regarded as mis-

branded if at any time prior to dispensing the following conditions are not met:

"(1) The label bears the legend, 'Caution: Federal law prohibits dispensing without a prescription'; and

"(2) The labeling bears full disclosure information as required by § 1.106(b)(3)(i) of this chapter, and especially appropriate warnings regarding vitamin D toxicity.

"(c) Preparations containing 400 or less IU of vitamin D per dosage unit will be regarded as misbranded if their recommended daily intake exceeds 400 IU.

"(d) Foods which are represented for use solely under medical supervision to meet nutritional requirements of persons with poor vitamin D absorption may contain vitamin D not in excess of 1000 IU per dosage unit or recommended daily intake."

This is an action charging that the quoted regulations are invalid and seeking to enjoin their enforcement. The plaintiffs have moved for a preliminary injunction. The extraordinary relief thus sought must be denied upon the findings of fact and conclusions of law outlined below.

The plaintiffs are the National Nutritional Foods Association, a trade association composed of manufacturers, wholesalers, and retailers of vitamins and dietary supplements, and Solgar Co., Inc., a New York corporation which manufactures, distributes, and sells vitamin supplements.

The immediate background of the regulations in question begins with their promulgation by the Commissioner of Food and Drugs as proposed regulations in the Federal

Register dated December 19, 1972 (37 Fed.Reg. 26618). These regulations were corrected in minor detail in the Federal Register dated January 4, 1973 (38 Fed.Reg. 799). The Commissioner promulgated these regulations for the "efficient enforcement" of §§ 502(a), (f), and (j), and 503(b) of the Food and Drug Act as authorized by 21 U.S.C. § 371(a), under powers delegated to him by the Secretary. 21 C.F.R. § 2.120.

Explaining what were then his tentative views, the Commissioner said:

> "The acute and chronic toxicity of these vitamins is documented extensively in the medical literature. Vitamin A is available over the counter in dosage levels up to 10 times the recommended daily dietary allowance (RDA) of the Food and Nutrition Board, National Academy of Sciences—National Research Council (NAS-NRC) and vitamin D is available up to 60 times the RDA. The availability without prescription of these vitamins in high dosage levels contributes significantly to their misuse and the occurrence of serious adverse effects." (37 Fed.Reg. 26618 (1972)).

Adverse effects which the Commissioner found from excessive intake of Vitamin A include among others anorexia, growth retardation in children, migratory arthralgia and intracranial pressure. Adverse effects resulting from an excess of Vitamin D include anorexia, weight loss, polyuria, certain forms of calcification, hypertension, anemia, irreversible renal failure and death. In respect of Vitamin D the Commissioner noted that some of these severe effects are irreversible, and that the margin of safety between nutritional requirements and toxic levels is small.

Appendix B

An extensive bibliography listing the scientific articles used by the FDA in formulating its proposed regulation was placed on public view.

When the Commissioner published the proposed rules and their rationale he provided 60 days in which interested parties might comment, in accordance with the rulemaking provisions of the Administrative Procedure Act. (5 U.S.C. § 553(c)). The response was massive. Over 2500 comments were received. Of special interest for present purposes, the two plaintiffs herein, as well as other drug companies, presented substantial amounts of factual material and expert opinion opposing the proposed regulations. Others made extensive submissions pro and con. The mass of these presentations has been lodged with the court and fills some 45 manila folders.

The commentators, responding to the Commissioner's invitation, fall into three general categories:

(1) Those who agreed that prescription levels are necessary and that those proposed by the FDA were suitable. This group included official representatives of the American Academy of Pediatrics, the American Medical Association, the American Dietetic Association, and other medical and scientific experts.[1]

(2) Those who agreed that prescription levels were necessary but argued that the levels should be higher than those set by the FDA. These groups included most drug manufacturers and trade associations as well as a few indi-

[1] One group of commentators, mainly scientists and medical researchers, argued that the Commissioner should actually set lower unit limits for prescription sales.

vidual consumers. Several of these commentators made a critical review of the scientific literature used by the FDA, arguing generally that "toxicity below 50,000 IU daily for vitamin A was rare and that vitamin D toxicity reports would not support the vitamin D level proposed." (38 Fed. Reg. 20724 (1973)).

(3) Those who disagreed with the proposal entirely, arguing that vitamins are foods and that individuals should have the right to use any amounts they desire. Most individual consumer comments as well as comments from health food retailers fell in this category. Such commentators pointed out that the dosage level of vitamins in many foods is higher than the prescription level—for example, 100 grams of liver contains at least 24,000 I.U. of vitamin A—and that a limitation on vitamins and not on food substances is irrational.

Having considered the factual and legal materials submitted for his expert judgment, the Commissioner concluded that the regulations now assailed should be adopted. (38 Fed.Reg. 20723 (1973)). As grounds for this determination he noted that:

> "The concern of the Food and Drug Administration is the availability of vitamin A and vitamin D in large dosage units in medicinal forms, i. e., capsules and tablets, particularly in view of the multiplicity of other sources of this vitamin in the daily diet. The convenience of ingestion in this form on a routine basis encourages excessive intake of these vitamins far beyond the average amounts ingested in normal diets of conventional food over extended periods of time. Adequate amounts of vitamin A and vitamin D will con-

> tinue to be available as dietary supplements and are not being removed from the market place. The margins of safety provided in the levels established by this proposal were developed to take into account the wide ranges of vitamin content in foods and the dosage levels of vitamin A and vitamin D preparations that are usually implicated in toxic conditions." (38 Fed. Reg. 20724 (1973)).

Aiming to establish a reasonable "margin of safety," the Commissioner concluded that the limits he had proposed were prudent and efficacious.

In support of their claim that the Commissioner's regulations are not valid—and, more immediately, that the invalidity and resulting injury are clear enough to warrant the extraordinary relief of a preliminary injunction—the plaintiffs argue that:

(1) The Commissioner has exceeded his statutory authority in that he has improperly classified vitamins as drugs when they are in fact food substances and beyond the range of the Commissioner's authority to regulate.

(2) In any case vitamins, even if classified as drugs, cannot be defined as a "prescription drug" within the ambit of 21 U.S.C. § 353, which these regulations are designed to effectuate.

(3) The Commissioner's decision to require prescription limitations for vitamin A and D is not supported by the medical and scientific evidence and is factually unreasonable.

None of these claims can be sustained.

[1] (1) Plaintiffs argue that vitamins are food substances and thus not subject to FDA regulations as "drugs." The Commissioner has made the judgment, however, that vitamins are a food only when used within the limits of the recommended daily allowance. At such a level they, like ordinary foods, are "nutrients." Above those levels they are deemed "appropriate only for therapeutic purposes and thus are properly classified as drugs" (38 Fed. Reg. 20723 (1973)).

21 U.S.C. § 321(g)(1) defines the term "drug" as follows:

> "(A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clauses (A), (B), or (C) of this paragraph; but does not include devices or their components, parts, or accessories."

[2] This language is to be construed liberally in the light of the statutory concern for health and safety. See, e. g., United States v. Bacto-Unidisk, 394 U.S. 784, 792, 89 S.Ct. 1410, 22 L.Ed.2d 726 (1969); United States v. Sullivan, 332 U.S. 689, 693-697, 68 S.Ct. 331, 92 L.Ed. 297 (1948); United States v. Dotterweich, 320 U.S. 277, 280, 64 S.Ct. 134, 88 L.Ed. 48 (1943); United States v. Diapulse Cor-

poration of America, 457 F.2d 25, 28 (2d Cir. 1972). Quite apart from rules of construction, and leaving aside the lay knowledge that the likeliest place to go for vitamins is the "drug store," the products here are squarely within the literal language and evident meaning of the statute. If there were more doubt, the question would surely be one on which to weigh further against plaintiffs the everyday experience and judgmental responsibility of the Commissioner. N. L. R. B. v. Hearst Publications, 322 U.S. 111, 130, 64 S.Ct. 851, 88 L.Ed. 1170 (1944).

[3, 4] (2) Plaintiffs argue that even if Vitamins A and D are to be denominated "drugs," they do not fall within the statutory definition of a "prescription drug" subject to the kind of regulatory authority the Commissioner has asserted. The provision in question is 21 U.S.C. § 353, which states in relevant part:

> "(b)(1) A drug intended for use by man which—
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> • • • • •
>
> "(B) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug
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> • • • • •
>
> shall be dispensed • • • upon • • • prescription • • • ."

It is plain that the concern over "potentiality for harmful effect" imposes broad responsibility upon the Commissioner to safeguard human health. He has acted well within that duty in setting upper limits at a level convenient and

agreeable for affected consumers (including those who may want two or three pills to reach levels recommended by the most exuberant of vitamin enthusiasts) while affording protection through a safety margin against dangers which have been universally acknowledged even if they are not mechanically quantifiable at a precisely agreed level. The Commissioner is not only entitled but required to be at least as prudent as lay understanding of human behavior would dictate. He knows that almost nobody has a reliably identified need for as much as—let alone more than—10,000 daily units of Vitamin A.[2] He knows, because we all do, of the prevalent wisdom among us pill swillers that "if one is good, two are better." He knows such things as the widely held belief in the efficacy of Vitamin A for acne, and he knows that moderation may not be the chief attribute of those troubled by this condition. Knowing such obvious things and other matters less patent, the Commissioner is not required to circumscribe his responsibilities in terms solely of the completely "rational" consumer. He may and he must consider the "potentiality for harmful effect" through excessive use to the merely "average" man and even to the substantial numbers of us who help create the average by falling below it.

[5] Both plaintiffs and defendants agree that toxicity exists at some level. Plaintiffs' quarrel with the Commissioner is over the dosage point at which some restrictions would become prudent. The Commissioner, however, is not required to set the over-the-counter limit at a maximum which the consumer (be he old, young, weak or strong)

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[2] Comparable observations apply to Vitamin D.

might withstand. See United States v. Bodine Products, 206 F.Supp. 201, 207 (D.Ariz. 1962). A substantial margin of safety probably should—certainly may—be used, at least in a case like this, where it can have only beneficial effects for the Commissioner's paramount subject of health.

> "One making a rule for the future which in practical effect will determine whether millions of people shall eat something every day may reasonably refuse to subject the general public to even slight risks and small deceptions." Atlas Powder v. Ewing, 201 F.2d 347, 355 (3d Cir. 1952).

[6] (3) Plaintiffs launch a variety of procedural and "evidentiary" attacks upon the factual premises of the regulations. None of these seems meritorious.

The Commissioner's judgments about safety levels (in the admittedly uncertain and debated state of knowledge) and consumer habits are solidly grounded. If the question were for *de novo* decision, the court would probably decide as he did. But it is enough to say his determinations are reasonable and rational.

Though they had ample opportunity to present anything pertinent to the FDA, plaintiffs urge that they should be permitted to make a new record here, presumably to show that the Commissioner must be denounced as "arbitrary and capricious" on the basis of materials he was not invited to look at. The argument would appear to lack merit, but it need not be resolved finally for present purposes. Moving with the relative dispatch required by the occasion, the court has considered all the materials submitted, including those the Commissioner was not given. The result

remains that the rationality of the questioned regulations unquestionably survives the effort to block them by a preliminary injunction.

The balance of the equities is heavily against the plaintiffs. They have offered some unimpressive figures for the expense of relabeling their vitamin bottles and putting up new pill strengths—for all of which the Commissioner gave long notice before the effective date of his regulations. Informed that the figures were vague and unenlightening, plaintiffs expanded the alleged numbers *in a brief*. The result remains less than imposing.

If people want 20,000 or 30,000 units of Vitamin A, they can dose themselves with two or three pills—or, better still, see a doctor first. As the court has attempted to indicate, this sort of mild obstacle to the swallowing of toxic amounts seems compellingly sensible—a quality not necessarily objectionable for regulatory decisions.

In short, the public interest in health quite overwhelms the financial concerns plaintiffs urge.

Beyond that, the likelihood that plaintiffs will succeed in this action seems negligible.

There are, then, no grounds for, and powerful grounds against, a preliminary injunction.

Plaintiffs' motion is denied. So ordered.

APPENDIX C

Opinion in *National Nutritional Foods Association* v. *Weinberger* (Granting Defendants' Motion) Officially Reported at 376 F.Supp. 142 (SDNY, 1974)

FRANKEL, District Judge.

On October 1, 1973, regulations of the Food and Drug Administration became effective requiring that preparations of Vitamin A and Vitamin D in excess of 10,000 IU (international units) per dosage unit and 400 IU per dosage unit, respectively, be restricted to prescription sale and that such vitamins be labeled accordingly. 21 C.F.R. §§ 3.94 and 3.95 (1973). The regulations were declared to have been promulgated to implement the "efficient enforcement" of §§ 502(a), (f), and (j) and 503(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 352(a), (f), and (j) and 353(b), under the general authority of the Act's § 701 (a), 21 U.S.C. § 371(a), and pursuant to powers delegated to the Commissioner by 21 C.F.R. § 2.120(a)(1) (1973).

Plaintiffs, involved in the manufacture, distribution, and sale of Vitamins A and D, filed suit on August 6, 1973, seeking declaratory and injunctive relief against the regulations. Their motion for a preliminary injunction was denied on September 25, 1973. National Nutritional Foods Ass'n v. Weinberger, D.C., 366 F.Supp. 1341, aff'd 491 F.2d 845 (2d Cir., 1973).

Defendants have now moved for summary judgment dismissing the complaint. Counsel have made extensive submissions, and the court has heard further oral argument, supplementing the things read and heard on the motion for a preliminary injunction. For reasons hereinafter outlined, the complaint is now to be dismissed.

Appendix C

I.

Plaintiffs claim that the questioned regulations were issued by the Commissioner without statutory authority. They argue that the legislative history of the prescription drug statute, 21 U.S.C. § 353(b)(1)[1] reveals a purpose to prohibit regulations of this kind. The history shows, plaintiffs say, that the prescription requirement was meant to be for case-by-case determination in court, not for administrative rules like those before us. This intended limitation, they argue, may not be surmounted or avoided by the more general authority of the Commissioner to issue regulations under 21 U.S.C. § 371(a). These contentions have substance. Having considered them, however, the court concludes that the legislative history is by no means clear enough to pre-

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[1] "(b)(1) A drug intended for use by man which—

"(A) is a habit-forming drug to which section 352(d) of this title applies; or

"(B) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

"(C) is limited by an approved application under section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such drug,

shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale."

clude a look at the statutory text,[2] and that the legislative mandate as a whole sustains the agency's position.

The Food, Drug and Cosmetic Act (the Copeland Act), 21 U.S.C. § 301 et seq., was passed in 1938, superseding a 1906 statute touching the subject (the Wiley Act, c. 3915, 34 Stat. 768). The new Act was designed to respond to "profound changes in methods of manufacturing and selling foods and drugs" which had developed since 1906 and to remedy "textual weaknesses in the measure that were not foreseen when it was enacted." 79 Cong.Rec. 4758 (remarks of Sen. Copeland); see generally Jackson, Food and Drug Legislation in the New Deal (1970). Section 503(b) of the Act, 21 U.S.C. § 353(b) (the prescription drug statute), was further amended in 1951 by the Durham-Humphrey Amendment, c. 578, 65 Stat. 648 (1951). This amendment and its history are the central subjects of plaintiffs' case.

The general purpose of the 1951 legislation was to adapt the Food, Drug and Cosmetic Act—

> "to deal realistically with the labelling and dispensing of drugs that may be sold only upon the prescription of licensed practitioners. Its provisions are remedial in the sense that they are intended to protect the public from abuses in the sale of potent prescription medicines. They will also relieve retail pharmacists of unnecessary restrictions in the dispensing of drugs that are safe for use without medical supervision." S.Rep. No. 946, 82d Cong., 1st Sess. cited in 1951 U.S.Code Cong. and Admin.Serv. p. 2454.

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[2] See Greenwood v. United States, 350 U.S. 366, 374, 76 S.Ct. 410, 100 L.Ed. 412 (1956) (Frankfurter, J.).

Accordingly, the amended section 503 created a new prescription requirement encompassing a statutory definition of drugs that may be dispensed only on prescription and specifying the conditions under which these drugs may be dispensed. Before, the law had simply commanded that the labeling of drugs bear adequate directions for use. While the Commission had provided some regulatory suasion,[3] it had been for the drug manufacturer to make the primary determination as to whether a prescription was necessary; the resulting lack of uniformity had left the retail druggist adrift in identifying his statutory (and health) obligations. One manufacturer might determine that a prescription legend was required for the same drug that a competing manufacturer considered suitable for over-the-counter sale. See H.R.Rep.No.700, 82d Cong., 1st Sess. 3 (1951). As originally proposed, in H.R. 3298, the amended § 503(b) would have conferred authority on the F.D.A. to issue an administrative list of drugs requiring prescription prior to sale. While this provision was opposed by many drug manufacturers, it remained in the bill as reported out by the House Committee on Interstate and Foreign Commerce. Among the considerations which influenced the Committee in its decision to retain this aspect of the bill was the recognition that "the task of determining which drugs shall be sold only on prescription is, in its nature, essentially a legislative or rule-making function, unsuited for solution solely through the judicial process." H.R.Rep.No.700, *supra* at 10.

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[3] In 1944, the F.D.A. promulgated regulations designed to provide some guidance as to what drugs would be exempted from various warning requirements on their labels if only prescription sale was allowed. These standards were similar to those later incorporated in the Durham-Humphrey Amendment. See 21 C.F.R. § 1.106(b)(1) and (b)(2)(ii) (1949).

A minority report asserted that "the present method which leaves this determination [of whether a prescription is required] to the courts, should be left unchanged except that a proper standard to be applied in determining whether a drug is dangerous should be incorporated in the statute." *Id.* at 28. The minority argued that providing the Administrator with power to issue regulations was a "dangerous delegation of authority" which would "add to present difficulties by increased bureaucratic regulation." *Id.*

H.R.3298 reached the floor of the House on July 31, 1951, 97 Cong.Rec. 9235 (1951). The minority view on handling the prescription requirement gathered support, on stated grounds both of general principle and of specific hostility to the then Administrator. On August 1, Congressman O'Hara of Minnesota introduced an amendment to strike the sections of the bill providing for the promulgation of an administrative list of drugs requiring a prescription for sale. The amendment carried. In its amended form H.R. 3298 was passed by the House and sent to the Senate, where it was reported out favorably and passed with minor amendments (and no significant debate) on October 15, 1951.

The Senate Committee which considered H.R.3298 as passed by the House had before it both H.R.3298 and a companion Senate Bill, S. 1186 with various amendments in the nature of a substitute by Senator Humphrey designed to reintroduce the administrative list. While the Committee ultimately accepted the House version, it noted that the statutory definition *simpliciter* would be difficult or impossible to administer. The Committee Report explicitly contemplated the formulation of implementing regulations under 21 U.S.C. § 371(a) to effectuate the statutory objective of protecting the public health:

"In order to give this general definition a more precise meaning so that it may be applied with greater uniformity by the drug trade the Administrator can exercise the authority he has under section 701(a) of the Federal Food, Drug, and Cosmetic Act to issue interpretative regulations. It is to be understood that the inclusion of the statutory definition does not, of course, in any way derogate from the Administrator's authority to interpret and enforce the definition through the issuance of any regulations necessary or appropriate to protect the public from indiscriminate dispensing of drugs over the counter wher they may be unsafe for use without the supervision of a practitioner licensed by law to administer such drugs.

"As previously stated, the committee considered S. 1186 together with H.R.3298. S. 1186 would have authorized the Federal Security Administrator to list by name or class the drugs which he considered within the statutory definition. The grant of such administrative authority was objected to as an unnecessary regulation of the drug industry, and the committee concluded that administrative listing is not necessary at this time. It was felt that the statutory definition, together with the authority to make interpretative regulations, could bring an end to the existing confusion in drug labeling and that uniformity can be achieved through cooperative efforts of the drug industry and the Food and Drug Administration working under the statutory plan. If the present confusion is not ended by this legislation it will then be time enough to consider the need for the administrative listing approach.

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"Furthermore, in determining whether a drug is safe for use without medical supervision, there must be taken into consideration not only the drug's toxicity, but also other potentialities for harmful effect, the method by which it is used and the collateral measures necessary to its safe use. The broad language of the definition contained in this subparagraph is intended to comprehend all drugs that in fact should be administered under medical supervision in order to insure their safe use. *Such difficult borderline cases as may arise under this definition can be dealt with under the interpretative and rule-making power provided for in section 701(a) of the act.*" S.Rep.No.946, 82d Cong., 1st Sess., cited in 1951 U.S.Code Cong. and Admin.Serv. pp. 2457, 2461 (emphasis added).

In these expressions at least, there was a plain understanding that whatever specific rule-making powers were given to the F.D.A., the commissioner would be required and expected to use his § 701(a) power "to promulgate regulations for the efficient enforcement of this Act" in making the prescription requirement effective. As for the House, if it rejected the broad project of an "administrative list," it left § 701(a) intact and nowhere indicated a purpose to render that section inoperative for purposes of the new prescription provision.[4]

[1] Wherever the legislative history alone might leave us, the Commissioner's position finds solid support in § 701(a) of the Act, 21 U.S.C. § 371(a), and judicial as

[4] Contemporary trade circles recognized that this would be the case as well. See Dunn, The New Prescription Drug Law, 6 Food, Drug, Cosm. L.J. 951, 955-56 (1951).

well as administrative constructions of this provision. Section 701(a) empowers the Commissioner, as delegee of the Secretary of Health, Education and Welfare, 21 C.F.R. § 2.120 (1973), "to promulgate regulations for the efficient enforcement of" the Act, including the Act's prescription requirement in § 353(b). Plaintiffs argue this is authority for mere "housekeeping" provisions, and they contrast subsection (e)[5] with subsection (a) of § 701 to

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[5] § 701(e), 21 U.S.C. § 371(e) sets up structured procedures for promulgating regulations for specified purposes. Regulations issued under six specified statutes require that any proposed regulations be published by the Secretary. Within 30 days, if objection is received, a public hearing will be held "for the purpose of receiving evidence relevant and material to the issues raised by such objections." The resulting regulations must contain detailed findings of fact and be based on substantial evidence in the record of the hearing. The original Act required that a hearing be held and a public record established before any regulations could be issued or amended. Later amendments allowed regulations meeting no opposition to be promulgated by this expedited mechanism. C. 143, 68 Stat. 55 (1954); c. 861, § 2, 70 Stat. 919 (1956); see Forte, Fair Hearing in Administrative Rule Making: A Recent Experience Under the Federal Food, Drug and Cosmetic and Fair Packaging and Labeling Acts, 1968 Duke L.J. 1, 11-17.

Six portions of the Act to which the § 701(e) procedures apply are: § 401, 21 U.S.C. § 341 (establishing definitional identity and quality standards for certain foods); § 403(j), 21 U.S.C. § 343(j) (labeling requirements for special dietary foods); § 404(a), 21 U.S.C. § 344(a) (emergency permit control system); § 406(a), 21 U.S.C. § 346 (establishment of tolerances for poisonous ingredients in food); § 502(d), 21 U.S.C. § 352(d) (designation of habit forming drug derivatives); § 502(h), 21 U.S.C. § 352(h) (packaging requirements for certain drugs). In a number of more recent grants of rule-making authority to the F.D.A. since the original Act was passed, the use of § 701(e) procedures was mandated by Congress. See, e. g., Fair Packaging and Labeling Act of 1967. 15 U.S.C. §§ 1454, 1455; Federal Hazardous Substances Act of 1960; *id.* §§ 1261, 1262, Color Additive Amendments of 1960, *id.* § 706.

In other substantive areas Congress recently gave the Secretary of Health, Education and Welfare power to elect whether to issue

buttress the argument.[6] But the contention is not only at war with a considerable body of administrative practice;[7]

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regulations under § 701(e) or under the less formal procedures of 5 U.S.C. § 553, e.g., Child Protection and Toy Safety Act of 1969, 15 U.S.C. §§ 1261(q), 1262(e)(1); Poison Prevention Packaging Act of 1970, 15 U.S.C. §§ 1471, 1474(a).

The scope of the 701(e) regulations is clear. The House Report on S. 5 (the basis for the 1938 Act) noted that:

> "Such regulations are not merely interpretive. They have the force and effect of law and must be observed. Their violation may result in the imposition of criminal penalties, or in the confiscation of the goods involved if shipped in interstate commerce, or in their exclusion from the country if imported."

H.R.Rep.No.2139, 75th Cong., 3d Sess., as cited in C. Dunn, Federal Food, Drug and Cosmetic Act: A Statement of Its Legislative Record 824 (1938).

[6] Plaintiffs argue that § 701(a) regulations are "interpretative" in the sense that they are promulgated without statutory authority and thus lack the force of law. This court accepts with alacrity the authoritative view that it is not profitable to explore the asserted distinction, Toilet Goods Association v. Gardner, 360 F.2d 677, 686 (2d Cir. 1966), aff'd, 387 U.S. 167, 87 S.Ct. 1526, 18 L.Ed.2d 704 (1967), which is "fuzzy at best." Shapiro, The Choice of Rulemaking or Adjudication in the Development of Administrative Policy, 78 Harv.L.Rev. 921, 930, 959-60 (1965). However labeled, the questioned regulations merit the respect owed an expert agency. See Skidmore v. Swift & Company, 323 U.S. 134, 136-140, 65 S.Ct. 161, 89 L.Ed. 124 (1944). No label can justify the claims, hereinafter considered, that the court should hear and determine these problems of medical and pharmacological judgment *de novo*.

[7] "The agency has promulgated a substantial number of rules under § 701(a)." Hamilton, Rulemaking on a Record by the Food and Drug Administration, 50 Texas L.Rev. 1132, 1133 n. 10 (1972). Among such regulations of clearly substantive proportions are those governing food nutritional labeling, 21 C.F.R. § 1.17 (1973), information panel labeling requirements, 21 C.F.R. § 1.8(d) (1973), food fat labeling, 21 C.F.R. § 1.18 (1973), specifications of the identity of products which may be sold under specific common or usual names, 21 C.F.R. § 102.1-8 (1973), Good Manufacturing Practice Regulations, 21 C.F.R. § 128 (1973), and the extensive

it is also contrary to controlling judicial authority. Weinberger v. Hynson, Westcott & Dunning, 412 U.S. 609, 93 S.Ct. 2469, 37 L.Ed.2d 207 (1973), sustained the F.D.A.'s authority under § 701(a) to create an "administrative summary judgment procedure" (p. 617, 93 S.Ct. 2469) having the drastic consequence, in cases to which it applied, of withdrawing approval of new drug applications without an evidentiary hearing. The administrative action was upheld as a valid instance of "particularizing statutory standards through the rulemaking process,"[8] deemed necessary and proper to prevent the "paralysis" of the administrative process which "would result if case-by-case battles in the courts were the only way to protect the public against unsafe or ineffective drugs." 412 U.S. p. 626, 93 S.Ct. p. 2481. Equally enlightening, if not technically "square"

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series of review mechanisms encompassing the Over-The-Counter drug review program, 21 C.F.R. § 130.301 (1973).

Wisconsin District Judge James E. Doyle has determined that the Good Manufacturing Practice Regulations specifying standards for "insanitary conditions," 21 C.F.R. 128(a)(A), promulgated under 701(a) are "not to be given automatic and decisive effect" in a criminal proceeding under 21 U.S.C. § 331(a). United States v. Everett Fisheries, Inc., No. 72-Cr.-109 (W.D.Wisc. May 30, 1973). Unlike the instant case, *Everett* was a criminal prosecution. The statutory language allegedly violated through the violation of the regulation was open to a variety of meanings and thus open to interpretation and argument. Cf. Pendergast and McMurray, The Constitutionality of the Good Manufacturing Practices Provision of the Federal Food, Drug & Cosmetic Act, 23 Bus Lawyer 445, 449-55 (1968); Barnard, Good Manufacturing Practices Regulations in the Food Industry, 22 Food Drug Cosm. L.J. 511, 513-14 (1967). It is also noteworthy that Judge Doyle's decision antedated Weinberger v. Hynson, Westcott & Dunning, considered just below in the text.

[8] The words were quoted, 412 U.S. at p. 620, 93 S.Ct. at p. 2478, from FPC v. Texaco, 377 U.S. 33, 39, 84 S.Ct. 1105, 12 L.Ed.2d 112 (1964), as stating a governing principle.

authority, is the pronouncement in Weinberger v. Bentex Pharmaceuticals, Inc., 412 U.S. 645, 653, 93 S.Ct. 2488, 2494, 37 L.Ed.2d 235 (1973), that the agency's power to determine "new drug" status in its own administrative proceedings was "implicit in the regulatory scheme" though "not spelled out in *haec verba* . . . ." Again, the construction was powerfully influenced by the recognition that a different view "would seriously impair FDA's ability to discharge the responsibilities placed on it by Congress." CIBA Corp. v. Weinberger, 412 U.S. 640, 643, 93 S.Ct. 2495, 2498, 37 L.Ed.2d 230 (1973).

Our Court of Appeals has recognized similarly that "the Commissioner has the power to issue binding interpretative regulations," citing to another example of the authority sustained under § 701(a), Abbott Laboratories v. Gardner, 387 U.S. 136, 87 S.Ct. 1507, 18 L.Ed.2d 681 (1967), and observing that "the particularization of a statute by rulemaking is not only acceptable in lieu of protracted piecemeal litigation . . . but it is the preferred procedure. . . ." CIBA-Geigy Corporation v. Richardson, 446 F.2d 466, 468 (2 Cir. 1971). This principle, applied in the instant case, implements our duty to treat the statute, with its paramount concern for life and health, "as a working instrument of government and not merely as a collection of English words." United States v. Dotterweich, 320 U.S. 277, 280, 64 S.Ct. 134, 136, 88 L.Ed. 48 (1943); see also United States v. Bacto-Unidisk, 394 U.S. 784, 798, 89 S.Ct. 1410, 22 L.Ed. 2d 726 (1969); United States v. Sullivan, 332 U.S. 689, 696, 68 S.Ct. 331, 92 L.Ed. 297 (1948); Permian Basin Area Rate Cases, 390 U.S. 747, 776, 88 S.Ct. 1344, 20 L.Ed. 2d 312 (1968). The recent approval of legislative rulemaking power under a section of the Truth In Lending

Act very like § 701(a) in language, Mourning v. Family Publications Service, Inc., 411 U.S. 356, 369, 93 S.Ct. 1652, 36 L.Ed.2d 318 (1973), adds further support to the Commissioner's position here, as does the D.C. Circuit's determination that the Federal Trade Commission possesses substantive rulemaking power although the statute does not explicitly say so. National Petroleum Refiners Association v. F. T. C., 482 F.2d 672, 676-677, 689-691 (D.C.Cir. 1973), pet. for cert. filed, 415 U.S. 951, 94 S.Ct. 1475, 39 L.Ed.2d 567 (1973) (No. 806).

If the foregoing citations do not dictate mechanically the result herein, they point the clear path to decision. The "case-by-case battles in the courts" deemed compulsory by plaintiffs would have to be borne if the law required them. The result would be, of course, a rickety apparatus of non-regulation, with judges making disparate and uninformed decisions about when prescriptions should or should not be required. Such *de novo* court hearings could in no way inure "to [those] interests of the public that Congress was anxious to protect," Weinberger v. Bentex Pharmaceuticals, et al., 412 U.S. 645, 653, 93 S.Ct. 2488, 2494, 37 L.Ed.2d 235 (1973). It seems fortunate that the Act, read sensibly and as a whole, requires no such unhappy interpretation.

II.

[2, 3] Plaintiffs contend that they should have a *de novo* "trial," preceded by considerable discovery, to test the questioned regulations. There is no warrant for such explorations or for an evidentiary hearing of any kind. The agency was not required to hold a trial-type hearing before issuing its regulations, and none is either required or permitted in the court. It is sufficient that the public, including

the plaintiffs, were "given a significant opportunity prior to promulgation of . . . [the] . . . rule[s] to ventilate the policy and empirical issues at stake through written submissions." National Petroleum Refiners Association v. Federal Trade Comm., 482 F.2d 672, 692 (D.C. Cir. 1973), pet. for cert. filed, 415 U.S. 951, 94 S.Ct. 1475, 39 L.Ed.2d 567 (No. 806). Unlike the rare cases in which the absence of an administrative record may require the taking of evidence in court, e. g., Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402, 419-420, 91 S.Ct. 814, 28 L.Ed.2d 136 (1971), there is a voluminous and unstinting record here. Some 46 volumes in size, "it consists of the submissions made in response to the invitations issued for written comments." Automotive Parts & Accessories v. Boyd, 132 U.S.App.D.C. 200, 206, 407 F.2d 330, 336 (1968). Plaintiffs had full opportunity to present everything they thought germane. The agency, referring to the extensive materials it received, has sufficiently "articulate[d] its bases and purposes" in promulgating the regulations. Buckeye Power, Inc. v. EPA, 481 F.2d 162, 170-171 (6th Cir. 1973); see also Associated Indus. of N. Y. S., Inc. v. Dept. of L., 487 F.2d 342, 354 (2d Cir. 1973); Mobil Oil Corporation v. Federal Power Commission, 152 U.S.App.D.C. 119, 469 F.2d 130, 140 (1972), cert. den., 412 U.S. 931, 93 S.Ct. 2749, 37 L.Ed. 2d 159 (1973); International Engineering Company v. Richardson, 361 F.Supp. 818, 823-825 (D.D.C.1973).

[4] In rulemaking of this sort, where the regulations must stand unless they are deemed irrational or arbitrary and capricious, Associated Indus. of N. Y. S., Inc. v. Dept. of L., 487 F.2d 342, 348 (2d Cir. 1973); Bunny Bear, Inc. v. Peterson, 473 F.2d 1002, 1005-1006 (1st Cir. 1973); Unimed, Inc. v. Richardson, 147 U.S.App.D.C. 368, 458 F.2d 787, 789

(1972); Boating Industry Association v. Boyd, 409 F.2d 408, 411 (7th Cir. 1969); Citizens Band Association v. United States, 375 F.2d 43, 53-54 (9th Cir. 1967), it would be "sufficient that the regulations be supported by evidence in [the Commissioner's] files, or even by [his] experience." Consumers Union of United States, Inc. v. Consumer Product Safety Commission, 491 F.2d 810, at 812 (2d Cir. 1974). The case against plaintiffs is far stronger; in this domain of medical judgment, where certainty is not attainable and special caution to safeguard health is compelled, the prudent and easily managed restrictions the Commissioner has required are solidly supported by the materials that were before him and have been lodged with the court.

In any case it is clear that the main, if not the exclusive, object plaintiffs pursue is an exploration of the mental processes by which the Commissioner reached his results. Such explorations are rarely to be countenanced. United States v. Morgan, 313 U.S. 409, 422, 61 S.Ct. 999, 85 L.Ed. 1429 (1941); see also National Nutritional Foods Association v. Food and Drug Administration, 491 F.2d 1141 (2d Cir. 1974), especially when, as here, the Commissioner's rationale is sufficiently articulated to allow for meaningful judicial review. Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402, 420, 91 S.Ct. 814, 28 L.Ed.2d 136 (1971). No showing has been made to justify the extraordinary inquiry plaintiffs propose.

It is abundantly clear, then, that the court should, and it does, vacate plaintiffs' notice to depose defendant Commissioner or his designees at an examination to which deponents would be required to bring "any and all books, correspondence, records, medical reports and literature relating to their determination of the dosage levels of Vita-

mins A and D which are in issue . . . ." In sum, there are no factual issues to be tried. The administrative record was properly made. It is in no pertinent sense incomplete. It leads, as has been stated, to a ruling that the regulations are by no means arbitrary, capricious, or otherwise infirm. In so holding, the court has reconsidered the propositions of law underlying the denial of a preliminary injunction. Those premises are now adhered to and reaffirmed.

Plaintiffs' notice of deposition is vacated. Defendants' motion for summary judgment is granted. The complaint is dismissed.

So ordered.

APPENDIX D

Statutes

FEDERAL FOOD, DRUG, AND COSMETIC ACT, AS AMENDED

CHAPTER I—SHORT TITLE

SECTION 1. This Act may be cited as the Federal Food, Drug, and Cosmetic Act.

CHAPTER II—DEFINITIONS

SEC. 201 [321]. For the purposes of this Act—

(a)(1) The term "State", except as used in the last sentence of section 702(a), means any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

(2) The term "Territory" means any Territory or possession of the United States, including the District of Columbia, and excluding the Commonwealth of Puerto Rico and the Canal Zone.

(b) The term "interstate commerce" means (1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body.

(c) The term "Department" means the U.S. Department of Health, Education, and Welfare.

(d) The term "Secretary" means the Secretary of Health, Education, and Welfare.

(e) The term "person" includes individual, partnership, corporation, and association.

(f) The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

(g)(1) The term "drug" means (A) articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C); but does not include devices or their components, parts, or accessories.

(2) The term "counterfeit drug" means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.

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*References in brackets [ ] are to title 21 U.S. Code.

is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

(l) The using, on the labeling of any drug or in any advertising relating to such drug, of any representation or suggestion that approval of an application with respect to such drug is in effect under section 505, or that such drug complies with the provisions of such section.

(m) The sale or offering for sale of colored oleomargarine or colored margarine, or the possession or serving of colored oleomargarine or colored margarine in violation of section 407(b) or 407(c).

(n) The using, in labeling, advertising or other sales promotion of any reference to any report or analysis furnished in compliance with section 704.

(o) In the case of a prescription drug distributed or offered for sale in interstate commerce, the failure of the manufacturer, packer, or distributor thereof to maintain for transmittal, or to transmit, to any practitioner licensed by applicable State law to administer such drug who makes written request for information as to such drug, true and correct copies of all printed matter which is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved by the Secretary. Nothing in this paragraph shall be construed to exempt any person from any labeling requirement imposed by or under other provisions of this Act.

(p) The failure to register as required by section 510.

(q)(1) The manufacture, compounding, or processing of a drug in violation of section 511(a); (2) the sale, delivery, or other disposition of a drug in violation of section 511(b); (3) the possession of a drug in violation of section 511(c); (4) the failure to prepare or obtain, or the failure to keep, a complete and accurate record with respect to any drug as required by section 511(d); (5) the refusal to permit access to or copying of any record as required by section 511(d); (6) the refusal to permit entry or inspection as authorized by section 511(d); or (7) the filling or refilling of any prescription in violation of section 511(e).

INJUNCTION PROCEEDINGS

SEC. 302 [332]. (a) The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown, and subject to the provisions of section 381 (relating to notice to opposite party) of Title 28, to restrain violations of section 301 of this title, except paragraphs (h), (i), and (j) of said section.

(b) In case of violation of an injunction or restraining order issued under this section, which also constitutes a violation of this Act, trial shall be by the court, or, upon demand of the accused, by a jury. Such trial shall be conducted in accordance with the practice and procedure applicable in the case of proceedings subject to the provisions of section 22 of such Act of October 15, 1914, as amended. [This section, which appeared as U.S.C., title 28, sec. 387, has been repealed. It is now covered by Rule 42(b), Federal Rules of Criminal Prodecure.]

PENALTIES

SEC. 303 [333]. (a) Any person who violates any of the provisions of section 301 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a

fine of not more than $1,000, or both such imprisonment and fine; but if the violation is committed after a conviction of such person under this section has become final such person shall be subject to imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine: *Provided, however,* That any person who, having attained his eighteenth birthday, violates section 301(q)(2) by selling, delivering, or otherwise disposing of any depressant or stimulant drug to a person who has not attained his twenty-first birthday shall, if there be no previous conviction of such person under this section which has become final, be subject to imprisonment for not more than two years, or a fine of not more than $5,000, or both such imprisonment and fine, and for the second or any subsequent conviction for such a violation shall be subject to imprisonment for not more than six years, or a fine of not more than $15,000, or both such imprisonment and fine.

(b) Not withstanding the provisions of subsection (a) of this section, in case of a violation of any of the provisions of section 301, with intent to defraud or mislead, the penalty shall (except in the case of an offense which is subject to the provisions of the proviso to subsection (a) relating to second or subsequent offenses) be imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine.

(c) No person shall be subject to the penalties of subsection (a) of this section, (1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith, unless he refuses to furnish on request of an officer or employee duly designated by the Secretary the name and address of the person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him; or (2) for having violated section 301 (a) or (d), if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 301(a), that such article is not adulterated or misbranded, within the meaning of this Act, designating this Act, or to the effect, in case of an alleged violation of section 301(d), that such article is not an article which may not, under the provisions of section 404 or 505, be introduced into interstate commerce; or (3) for having violated section 301(a), where the violation exists because the article is adulterated by reason of containing a color additive not from a batch certified in accordance with regulations promulgated by the Secretary under this Act, if such person establishes a guaranty or undertaking signed by, and containing the name and address of, the manufacturer of the color additive, to the effect that such color additive was from a batch certified in accordance with the applicable regulations promulgated by the Secretary under this Act; or (4) for having violated section 301 (b), (c), or (k) by failure to comply with section 502(f) in respect to an article received in interstate commerce to which neither section 503(a) nor section 503(b)(1) is applicable, if the delivery or proffered delivery was made in good faith and the labeling at the time thereof contained the same directions for use and warning statements as were contained in the labeling at the time of such receipt of such aticle; or (5) for having violated section 301(i)(2) if such person acted in good faith and had no reason to believe that use of the

punch, die, plate, stone, or other thing involved would result in a drug being a counterfeit drug, or for having violated section 301(i)(3) if the person doing the act or causing it to be done acted in good faith and had no reason to believe that the drug was a counterfeit drug.

SEIZURE

SEC. 304 [334]. (a)(1) Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of section 404 or 505, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, or libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found: *Provided, however,* That no libel for condemnation shall be instituted under this Act, for any alleged misbranding if there is pending in any court a libel for condemnation proceeding under this Act based upon the same alleged misbranding, and not more than one such proceeding shall be instituted if no such proceeding is so pending, except that such limitations shall not apply (A) when such misbranding has been the basis of a prior judgment in favor of the United States, in a criminal, injunction, or libel for condemnation proceeding under this Act, or (B) when the Secretary has probable cause to believe from facts found, without hearing, by him or any officer or employee of the Department that the misbranded article is dangerous to health, or that the labeling of the misbranded article is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer. In any case where the number of libel for condemnation proceedings is limited as above provided the proceeding pending or instituted shall, on application of the claimant, seasonably made, be removed for trial to any district agreed upon by stipulations between the parties, or, in case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business to which the case shall be removed for trial.

(2) The following shall be liable to be proceeded against at any time on libel of information and condemned in any district court of the United States within the jurisdiction of which they are found:

(A) Any depressant or stimulant drug with respect to which a prohibited act within the meaning of section 301 (p) or (q) by any person had occurred,

(B) Any drug that is a counterfeit drug,

(C) Any container of such depressant or stimulant drug or of a counterfeit drug.

(D) Any equipment used in manufacturing, compounding, or processing a depressant or stimulant drug with respect to which drug a prohibited act within the meaning of section 301 (p) or (q), by the manufacturer, compounder, or processor thereof, has occurred, and

shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding.

REPORT OF MINOR VIOLATIONS

SEC. 306 [336]. Nothing in this Act shall be construed as requiring the Secretary to report for prosecution, or for the institution of libel or injunction proceedings, minor violations of this Act whenever he believes that the public interest will be adequately served by a suitable written notice or warning.

PROCEEDINGS IN NAME OF UNITED STATES; PROVISION AS TO SUBPOENAS

SEC. 307 [337]. All such proceedings for the enforcement, or to restrain violations, of this Act shall be by and in the name of the United States. Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any such proceeding.

CHAPTER IV—FOOD

DEFINITIONS AND STANDARDS FOR FOOD

SEC. 401 [341]. Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations[3] fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, and/or reasonable standards of fill of container: *Provided*, That no definition and standard of identity and no standard of quality shall be established for fresh or dried fruits, fresh or dried vegetables, or butter, except that definitions and standards of identity may be established for avocados, cantaloupes, citrus fruits, and melons. In prescribing any standard of fill of container, the Secretary shall give due consideration to the natural shrinkage in storage and in transit of fresh natural food and to need for the necessary packing and protective material. In the prescribing of any standard of quality for any canned fruit or canned vegetable, consideration shall be given and due allowance made for the differing characteristics of the several varieties of such fruit or vegetable. In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Secretary shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label. Any definition and standard of identity prescribed by the Secretary for avocados, cantaloupes, citrus fruits, or melons shall relate only to maturity and to the effects of freezing.

ADULTERATED FOOD

SEC. 402 [342]. A food shall be deemed to be adulterated—

(a) (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is

[3] F.D.C. Regs., parts 10, 14-20, 22, 26, 27, 29, 31, 36, 37, 42, 45, 46, 51, 53.

which is in or on confectionery by reason of its use for some practical functional purpose in the manufacture, packaging, or storage of such confectionery if the use of the substance does not promote deception of the consumer or otherwise result in adulteration or misbranding in violation of any provision of this Act: *And provided further*, That the Secretary may, for the purpose of avoiding or resolving uncertainty as to the application of this clause, issue regulations allowing or prohibiting the use of particular nonnutritive substances.

(e) If it is oleomargarine or margarine or butter and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed substance, or such oleomargarine or margarine or butter is otherwise unfit for food.

SEC. 403 [343]. A food shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

(b) If it is offered for sale under the name of another food.

(c) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated.

(d) If its container is so made, formed, or filled as to be misleading.

(e) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(f) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(g) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 401, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the defintion and standard, and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.

(h) If it purports to be or is represented as—

(1) a food for which a standard of quality has been prescribed by regulations as provided by section 401, and its quality falls below such standard, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard; or

(2) a food for which a standard or standards of fill of container have been prescribed by regulations as provided by section 401, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard.

(i) If it is not subject to the provisions of paragraph (g) of this section unless its label bears (1) the common or usual name of the

food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient; except that spices, flavorings, and colorings, other than those sold as such, may be designated as spices, flavorings, and colorings without naming each: *Provided*, That, to the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

(j) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary determines to be, and by regulations [5] prescribes as, necessary in order fully to inform purchasers as to its value for such uses.

(k) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact: *Provided*, That to the extent that compliance with the requirements of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary. The provisions of this paragraph and paragraphs (g) and (i) with respect to artificial coloring shall not apply in the case of butter, cheese, or ice cream. The provisions of this paragraph with respect to chemical preservatives shall not apply to a pesticide chemical when used in or on a raw agricultural commodity which is the produce of the soil.

(l) If it is a raw agricultural commodity which is the produce of the soil, bearing or containing a pesticide chemical applied after harvest, unless the shipping container of such commodity bears labeling which declares the presence of such chemical in or on such commodity and the common or usual name and the function of such chemical: *Provided, however*, That no such declaration shall be required while such commodity, having been removed from the shipping container, is being held or displayed for sale at retail out of such container in accordance with the custom of the trade.

(m) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 706.

EMERGENCY PERMIT CONTROL

SEC. 404[344]. (a) Whenever the Secretary finds after investigation that the distribution in interstate commerce of any class of food may, by reason of contamination with micro-organisms during the manufacture, processing, or packing thereof in any locality, be injurious to health, and that such injurious nature cannot be adequately determined after such articles have entered interstate commerce, he then, and in such case only, shall promulgate regulations providing for the issuance, to manufacturers, processors, or packers of such class of food in such locality, of permits to which shall be attached such conditions governing the manufacture, processing, or packing of such class of food, for such temporary period of time, as may be necessary to protect the public health; and after the effective date of such regulations, and during such temporary period, no person shall introduce or deliver for introduction into interstate commerce any such food manufactured, processed, or packed by any such manufacturer,

[5] F.D.C. Regs., part 125.

ances or exemptions have not been established under section 408 of the Federal Food, Drug, and Cosmetic Act, the amendment to section 402(a) of such Act made by section 2 of this Act shall not be effective—

(1) for the period of one year following the date of the enactment of this Act; or

(2) for such additional period following such period of one year, but not extending beyond two years after the date of the enactment of this Act, as the Secretary of Health, Education, and Welfare may prescribe on the basis of a finding that conditions exist which necessitate the prescribing of such additional period.

FOOD ADDITIVES

Unsafe Food Additives

SEC. 409 [348]. (a) A food additive shall, with respect to any particular use or intended use of such additives, be deemed to be unsafe for the purposes of the application of clause (2)(C) of section 402(a), unless—

(1) it and its use or intended use conform to the terms of an exemption which is in effect pursuant to subsection (i) of this section; or

(2) there is in effect, and it and its use or intended use are in conformity with, a regulation [11] issued under this section prescribing the conditions under which such additive may be safely used.

While such a regulation relating to a food additive is in effect, a food shall not, by reason of bearing or containing such an additive in accordance with the regulation, be considered adulterated within the meaning of clause (1) of section 402(a).

Petition To Establish Safety

(b)(1) Any person may, with respect to any intended use of a food additive, file with the Secretary a petition proposing the issuance of a regulation prescribing the conditions under which such additive may be safely used.

(2) Such petition shall, in addition to any explanatory or supporting data, contain—

(A) the name and all pertinent information concerning such food additive, including, where available, its chemical indentity and composition;

(B) a statement of the conditions of the proposed use of such additive, including all directions, recommendations, and suggestions proposed for the use of such additive, and including specimens of its proposed labeling;

(C) all relevant data bearing on the physical or other technical effect such additive is intended to produce, and the quantity of such additive required to produce such effect;

(D) a description of practicable methods for determining the quantity of such additive in or on food, and any substance formed in or on food, because of its use; and

[11] F.D.C. Regs., part 121.

(E) full reports of investigations made with respect to the safety for use of such additive, including full information as to the methods and controls used in conducting such investigations.

(3) Upon request of the Secretary, the petitioner shall furnish (or, if the petitioner is not the manufacturer of such additive, the petitioner shall have the manufacturer of such additive furnish, without disclosure to the petitioner), a full description of the methods used in, and the facilities and controls used for, the production of such additive.

(4) Upon request of the Secretary, the petitioner shall furnish samples of the food additive involved, or articles used as components thereof, and of the food in or on which the additive is proposed to be used.

(5) Notice of the regulation proposed by the petitioner shall be published in general terms by the Secretary within thirty days after filing.

Action on the Petition

(c)(1) The Secretary shall—

(A) by order establish a regulation [12] (whether or not in accord with that proposed by the petitioner) prescribing, with respect to one or more proposed uses of the food additive involved, the conditions under which such additive may be safely used (including, but not limited to, specifications as to the particular food or classes of food in or on which such additive may be used, the maximum quantity which may be used or permitted to remain in or on such food, the manner in which such additive may be added to or used in or on such food, and any directions or other labeling or packaging requirements for such additive deemed necessary by him to assure the safety of such use), and shall notify the petitioner of such order and the reasons for such action; or

(B) by order deny the petition, and shall notify the petitioner of such order and of the reasons for such action.

(2) The order required by paragraph (1) (A) or (B) of this subsection shall be issued within ninety days after the date of filing of the petition, except that the Secretary may (prior to such ninetieth day), by written notice to the petitioner, extend such ninety-day period to such time (not more than one hundred and eighty days after the date of filing of the petition) as the Secretary deems necessary to enable him to study and investigate the petition.

(3) No such regulation shall issue if a fair evaluation of the data before the Secretary—

(A) fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe: *Provided*, That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, of if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal, except that this proviso shall not apply with respect to the use of a substance as an ingredient of feed for animals which are raised for food production, if the Secretary finds (i) that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and

[12] F.D.C. Regs., part 121.

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(ii) that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsections (f) and (g)) in any edible portion of such animal after slaughter or in any food yielded by or derived from the living animal; or

(B) shows that the proposed use of the additive would promote deception of the consumer in violation of this Act or would otherwise result in adulteration or in misbranding of food within the meaning of this Act.

(4) If, in the judgment of the Secretary, based upon a fair evaluation of the data before him, a tolerance limitation is required in order to assure that the proposed use of an additive will be safe, the Secretary—

(A) shall not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the physical or other technical effect for which such additive is intended; and

(B) shall not establish a regulation for such proposed use if he finds upon a fair evaluation of the data before him that such data do not establish that such use would accomplish the intended physical or other technical effect.

(5) In determining, for the purposes of this section, whether a proposed use of a food additive is safe, the Secretary shall consider among other relevant factors—

(A) the probable consumption of the additive and of any substance formed in or on food because of the use of the additive;

(B) the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet; and

(C) safety factors which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized as appropriate for the use of animal experimentation data.

Regulation Issued on Secretary's Initiative

(d) The Secretary may at any time, upon his own initiative, propose the issuance of a regulation [13] prescribing, with respect to any particular use of a food additive, the conditions under which such additive may be safely used, and the reasons therefor. After the thirtieth day following publication of such a proposal, the Secretary may by order establish a regulation based upon the proposal.

Publication and Effective Date of Orders

(e) Any order, including any regulation established by such order' issued under subsection (c) or (d) of this section, shall be published and shall be effective upon publication, but the Secretary may stay such effectiveness if, after issuance of such order, a hearing is sought with respect to such order pursuant to subsection (f).

Objections and Public Hearing

(f)(1) Within thirty days after publication of an order made pursuant to subsection (c) or (d) of this section, any person adversely affected by such an order may file objections thereto with the Secre-

[13] F.D.C. Regs., part 121.

tary, specifying with particularity the provisions of the order deemed objectionable, stating reasonable grounds therefor, and requesting a public hearing upon such objections. The Secretary shall, after due notice, as promptly as possible hold such public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public.

(2) Such order shall be based upon a fair evaluation of the entire record at such hearing, and shall include a statement setting forth in detail the findings and conclusions upon which the order is based.

(3) The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication, unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

Judicial Review

(g) (1) In a case of actual controversy as to the validity of any order issued under subsection (f), including any order thereunder with respect to amendment or repeal of a regulation issued under this section, any person who will be adversely affected by such order may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein such person resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a petition praying that the order be set aside in whole or in part.

(2) A copy of such petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall file in the court the record of the proceedings on which he based his order, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition the court shall have jurisdiction, which upon the filing of the record with it shall be exclusive, to affirm or set aside the order complained of in whole or in part. Until the filing of the record the Secretary may modify or set aside his order. The findings of the Secretary with respect to questions of fact shall be sustained if based upon a fair evaluation of the entire record at such hearing. The court shall advance on the docket and expedite the disposition of all causes filed therein pursuant to this section.

(3) The court, on such judicial review, shall not sustain the order of the Secretary if he failed to comply with any requirement imposed on him by subsection (f)(2) of this section.

(4) If application is made to the court for leave to adduce additional evidence, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper, if such evidence is material and there were reasonable grounds for failure to adduce such evidence in the proceedings below. The Secretary may modify his findings as to the facts and order by reason of the additional evidence so taken, and shall file with the court such modified findings and order.

(5) The judgment of the court affirming or setting aside, in whole or in part, any order under this section shall be final, subject to review

by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this section shall not, unless specifically ordered by the court to the contrary, operate as a stay of an order.

Amendment or Repeal of Regulations

(h) The Secretary shall by regulation [14] prescribe the procedure by which regulations under the foregoing provisions of this section may be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of such regulations.

Exemptions for Investigational Use

(i) Without regard to subsections (b) to (h), inclusive, of this section, the Secretary shall by regulation provide for exempting from the requirements of this section any food additive, and any food bearing or containing such additive, intended solely for investigational use by qualified experts when in his opinion such exemption is consistent with the public health.

CHAPTER V—DRUGS AND DEVICES

ADULTERATED DRUGS AND DEVICES

SEC. 501 [351]. A drug or device shall be deemed to be adulterated—

(a)(1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess; or (3) if it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if (A) it is a drug which bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of section 706(a), or (B) it is a color additive the intended use of which in or on drugs is for purposes of coloring only and is unsafe within the meaning of section 706(a).

(b) If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, except that whenever tests or methods of assay have not been prescribed in such compendium, or such tests or methods of assay as are prescribed are, in the judgment of the

[14] F.D.C. Regs., part 121.

Secretary, insufficient for the making of such determination, the Secretary shall bring such fact to the attention of the appropriate body charged with the revision of such compendium, and if such body fails within a reasonable time to prescribe tests or methods of assay which, in the judgment of the Secretary, are sufficient for purposes of this paragraph, then the Secretary shall promulgate regulations prescribing appropriate tests or methods of assay in accordance with which such determination as to strength, quality, or purity shall be made. No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefor set forth in such compendium, if its difference in strength, quality, or purity from such standards is plainly stated on its label. Whenever a drug is recognized in both the United States Pharmacopeia and the Homeopathic Pharmacopeia of the United States it shall be subject to the requirements of the United States Pharmacopeia unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopeia of the United States and not to those of the United States Pharmacopeia.

(c) If it is not subject to the provisions of paragraph (b) of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

(d) If it is a drug and any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor.

MISBRANDED DRUGS AND DEVICES

SEC. 502 [352]. A drug or device shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

(b) If in a package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(c) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(d) If it is for use by man and contains any quantity of the narcotic or hypnotic substance alpha-eucaine, barbituric acid, beta-eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marihuana, morphine, opium, paraldehyde, peyote, or sulfonmethane; or any chemical derivative of such substance, which derivative has been by the Secretary, after investigation, found to be, and by regulations [15] designated as, habit forming; unless its label bears the

[15] F.D.C. Regs., part 165.

name, and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement "Warning—May be habit-forming."

(e)(1) If it is a drug, unless (A) its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula), (i) the established name (as defined in subparagraph (2)) of the drug, if such there be, and (ii), in case it is fabricated from two or more ingredients, the established name and quantity of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including whether active or not, the established name and quantity or proportion of any bromides, ether, chloroform, acetanilide, acetophenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein: *Provided*, That the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this paragraph, shall apply only to prescription drugs; and (B) for any prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) is printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient: and *Provided*, That to the extent that compliance with the requirements of clause (A)(ii) or clause (B) of this subparagraph is impracticable, exemptions shall be estalished by regulations promulgated by the Secretary.

(2) As used in this paragraph (e), the term "established name", with respect to a drug or ingredient thereof, means (A) the applicable official name designated pursuant to section 508, or (B), if there is no such name and such drug, or such ingredient, is an article recognized in an official compendium, then the official title thereof in such compendium, or (C) if neither clause (A) nor clause (B) of this subparagraph applies, then the common or usual name, if any, of such drug or of such ingredient: *Provided further*, That where clause (B) of this subparagraph applies to an article recognized in the United States Pharmacopeia and in the Homeopathic Pharmacopeia under different official titles, the official title used in the United States Pharmacopeia shall apply unless it is labeled and offered for sale as a homeopathic drug, in which case the official title used in the Homeopathic Pharmacopeia shall apply.

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: *Provided*, That where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

(g) If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein: *Provided*, That the method of packing may be modified with the consent of the Secretary. Whenever a drug is recognized in both the United States Pharmacopeia and the Homeopathic Pharmacopeia

and (3) such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations which shall be issued by the Secretary in accordance with the procedure specified in section 701(e) of this Act: *Provided*, That (A) except in extraordinary circumstances, no regulation issued under this paragraph shall require prior approval by the Secretary of the content of any advertisement, and (B) no advertisement of a prescription drug, published after the effective date of regulations issued under this paragraph applicable to advertisements of prescription drugs, shall, with respect to the matters specified in this paragraph or covered by such regulations, be subject to the provisions of sections 12 through 17 of the Federal Trade Commission Act, as amended (15 U.S.C. 52-57). This paragraph (n) shall not be applicable to any printed matter which the Secretary determines to be labeling as defined in section 201(m) of this Act.

(o) If it is a drug and was manufactured, prepared, propagated, compounded, or processed in an establishment in any State not duly registered under section 510.

EXEMPTIONS IN CASE OF DRUGS AND DEVICES

SEC. 503 [353]. (a) The Secretary is hereby directed to promulgate regulations exempting from any labeling or packaging requirement of this Act drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs and devices are not adulterated or misbranded, under the provisions of this Act upon removal from such processing, labeling, or repacking establishment.

(b) (1) A drug intended for use by man which—

(A) is a habit-forming drug to which section 502(d) applies; or

(B) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(C) is limited by an approved application under section 505 to use under the professional supervision of a practitioner licensed by law to administer such drug,

shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

(2) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of section 502, except paragraphs (a), (i) (2) and (3), (k), and (l), and the packaging requirements of paragraphs (g) and (h), if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if

stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of paragraph (1) of this subsection.

(3) The Secretary may by regulation [17] remove drugs subject to section 502(d) and section 505 from the requirements of paragraph (1) of this subsection when such requirements are not necessary for the protection of the public health.

(4)[18] A drug which is subject to paragraph (1) of this subsection shall be deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement "Caution: Federal law prohibits dispensing without prescription." A drug to which paragraph (1) of this subsection does not apply shall be deemed to be misbranded if at any time prior to dispensing its label bears the caution statement quoted in the preceding sentence.

(5) Nothing in this subsection shall be construed to relieve any person from any requirement prescribed by or under authority of law with respect to drugs now included or which may hereafter be included within the classifications stated in section 3220 of the Internal Revenue Code (26 U.S.C. 3220), or to marihuana as defined in section 3238(b) of the Internal Revenue Code (26 U.S.C. 3238(b)).

NEW DRUGS

[See page 68 for "enactment date" as defined in the Drug Amendments Act of 1962.]

SEC. 505 [355]. (a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) is effective with respect to such drug.

(b) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such persons shall submit to the Secretary as a part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use; (2) a full list of the articles used as components of such drug; (3) a full statement of the composition of such drug; (4) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (5) such samples of such drug and of the articles used as components thereof as the Secretary may require; and (6) specimens of the labeling proposed to be used for such drug.

(c) Within one hundred and eighty days after the filing of an application under this subsection, or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either—

(1) approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) applies, or

(2) give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) on the question whether such application is approvable. If the applicant elects to accept

[17] F.D.C. Regs., part 130.
[18] See Sec. 1.106, F.D.C. Regs., part 1.

the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(d) If the Secretary finds, after due notice to the applicant in accordance with subsection (c) and giving him an opportunity for a hearing, in accordance with said subsection, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug si safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or (6) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through (6) do not apply, he shall issue an order approving the application. As used in this subsection and subsection (e), the term "substantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsioiy be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

(e) The Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any drug under this section if the Secretary finds (1) that clinical or other experience, tests, or other scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved; (2) that new evidence of clinical experience, not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was ap-

proved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved; or (3) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof; or (4) that the application contains any untrue statement of a material fact: *Provided*, That if the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the public health, he may suspend the approval of such spplication immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this priviso to suspend the approval of an application shall not be delegated. The Secretary may also, after due notice and opportunity for hearing to the applicant, withdraw the approval of an application with respect to any drug under this section if the Secretary finds (1) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports, in accordance with a regulation or order under subsection (j), or the applicant has refused to permit access to, or copying or verification of, such records as required by paragraph (2) of such subsection; or (2) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or (3) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of. Any order under this subsection shall state the findings upon which it is based.

(f) Whenever the Secretary finds that the facts so require, he shall revoke any previous order under subsection (d) or (e) refusing, withdrawing, or suspending approval of an application and shall approve such application or reinstate such approval, as may be appropriate.

(g) Orders of the Secretary issued under this section shall be served (1) in person by any officer or employee of the Department designated by the Secretary or (2) by mailing the order by registered mail or by certified mail addressed to the applicant or respondent at his last-known address in the records of the Secretary.

(h) [19] An appeal may be taken by the applicant from an order of the Secretary refusing or withdrawing approval of an application under this section. Such appeal shall be taken by filing in the United States court of appeals for the circuit wherein such applicant resides or has his principal place of business, or in the United States Court

[19] This amendment shall not apply to any appeal taken prior to the date of enactment of the Drug Amendments of 1962, enacted Oct. 10, 1962.

of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a written petition praying that the order of the Secretary be set aside. A copy of such petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court the record upon which the order complained of was entered, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition such court shall have exclusive jurisdiction to affirm or set aside such order, except that until the filing of the record the Secretary may modify or set aside his order. No objection to the order of the Secretary shall be considered by the court unless such objection shall have been urged before the Secretary or unless there were reasonable grounds for failure so to do. The finding of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive. If any person shall apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts by reason of the additional evidence so taken, and he shall file with the court such modified findings which, if supported by substantial evidence, shall be conclusive, and his recommendation, if any, for the setting aside of the original order. The judgment of the court affirming or setting aside any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of the Secretary's order.

(i) The Secretary shall promulgate regulations [20] for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. Such regulations may, within the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning such exemption upon—

(1) the submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, of preclinical tests (including tests on animals) of such drug adequate to justify the proposed clinical testing;

(2) the manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings; and

[20] F.D.C. Regs., part 130.3.

(e) If it is not a hair dye and it is, or it bears or contains, a color additive which is unsafe within the meaning of section 706(a).

MISBRANDED COSMETICS

SEC. 602 [362]. A cosmetic shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

(b) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(c) If any word, statement, or other information required by or under authority of this act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(d) If its container is so made, formed, or filled as to be misleading.

(e) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 706. This paragraph shall not apply to packages of color additives which, with respect to their use for cosmetics, are marketed and intended for use only in or on hair dyes (as defined in the last sentence of section 601(a)).

REGULATIONS MAKING EXEMPTIONS

SEC. 603 [363]. The Secretary shall promulgate regulations exempting from any labeling requirement of this act cosmetics which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such cosmetics are not adulterated or misbranded under the provisions of this act upon removal from such processing, labeling, or repacking establishment.

CHAPTER VII—GENERAL ADMINISTRATIVE PROVISIONS

REGULATIONS AND HEARINGS [28]

SEC. 701 [371]. (a) The authority to promulgate regulations for the efficient enforcement of this Act, except as otherwise provided in this section, is hereby vested in the Secretary.

(b) The Secretary of the Treasury and the Secretary of Health, Education, and Welfare shall jointly prescribe regulations for the efficient enforcement of the provisions of section 801, except as otherwise provided therein. Such regulations shall be promulgated in such manner and take effect at such time, after due notice, as the Secretary of Health, Education, and Welfare shall determine.

[28] Proposed F.D.C. Regs., part 2.

(c) Hearings authorized or required by this Act shall be conducted by the Secretary or such officer or employee as he may designate for the purpose.

(d) The definitions and standards of identity promulgated in accordance with the provisions of this Act shall be effective for the purposes of the enforcement of this Act, notwithstanding such definitions and standards as may be contained in other laws of the United States and regulations promulgated thereunder.

(e)(1) [29] Any action for the issuance, amendment, or repeal of any regulation under section 401, 403(j), 404(a), 406, 501(b), or 502 (d) or (h) of this Act shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall make such order public. Except as provided in paragraph (2), the order shall become effective at such time as may be specified therein, but not prior to the day following the last day on which objections may be filed under such paragraph.

(2) On or before the thirtieth day after the date on which an order entered under paragraph (1) is made public, any person who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections. Until final action upon such objections is taken by the Secretary under paragraph (3), the filing of such objections shall operate to stay the effectiveness of those provisions of the order to which the objections are made. As soon as practicable after the time for filing objections has expired the Secretary shall publish a notice in the Federal Register specifying those parts of the order which have been stayed by the filing of objections and, if no objections have been filed, stating that fact.

(3) As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person may be heard in person or by representative. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public. Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based. The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

(f)(1) In a case of actual controversy as to the validity of any order under subsection (e), any person who will be adversely affected by such order if placed in effect may at any time prior to the ninetieth

[29] Regulations issued under 201(v)(2)(C) and (3), 502(n)(3), 505(c), 706(b)(5)(C)(i), and 706(d) follow the procedure outlined in this subsection.

day after such order is issued file a petition with the Circuit Court of Appeals of the United States for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary thereupon shall file in the court the record of the proceedings on which the Secretary based his order, as provided in section 2112 of title 28, United States Code.

(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Secretary, and to be adduced upon the hearing, in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts, or make new findings, by reason of the additional evidence, so taken, and he shall file such modified or new findings, and his recommendation, if any, for the modification or setting aside of his original order, with the return of such additional evidence.

(3) Upon the filing of the petition referred to in paragraph (1) of this subsection, the court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently. If the order of the Secretary refuses to issue, amend, or repeal a regulation and such order is not in accordance with law the court shall by its judgment order the Secretary to take action with respect to such regulation, in accordance with law. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive [now covered by U.S.C. title 28, sec. 1254].

(4) The judgment of the court affirming or setting aside, in whole or in part, any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in sections 239 and 240 of the Judicial Code, as amended.

(5) Any action instituted under this subsection shall survive notwithstanding any change in the person occupying the office of Secretary or any vacancy in such office.

(6) The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law.

(g) A certified copy of the transcript of the record and proceedings under subsection (e) shall be furnished by the Secretary to any interested party at his request, and payment of the costs thereof, and shall be admissible in any criminal libel for condemnation, exclusion of imports, or other proceeding arising under or in respect of this Act, irrespective of whether proceedings with respect to the order have previously been instituted or become final under subsection (f).

EXAMINATIONS AND INVESTIGATIONS

SEC. 702 [372]. (a) The Secretary is authorized to conduct examinations and investigations for the purposes of this Act through officers and employees of the Department or through any health, food, or drug officer or employee of any State, Territory, or political subdivision

5 U.S.C.

§ 553. Rule making

(a) This section applies, according to the provisions thereof, except to the extent that there is involved—

(1) a military or foreign affairs function of the United States; or

(2) a matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.

(b) General notice of proposed rule making shall be published in the Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law. The notice shall include—

(1) a statement of the time, place, and nature of public rule making proceedings;

(2) reference to the legal authority under which the rule is proposed; and

(3) either the terms or substance of the proposed rule or a description of the subjects and issues involved.

Except when notice or hearing is required by statute, this subsection does not apply—

(A) to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice; or

(B) when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.

(c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose. When rules are required by statute to be made on the record after opportunity for an agency hearing, sections 556 and 557 of this title apply instead of this subsection.

(d) The required publication or service of a substantive rule shall be made not less than 30 days before its effective date, except—

(1) a substantive rule which grants or recognizes an exemption or relieves a restriction;

(2) interpretative rules and statements of policy; or

(3) as otherwise provided by the agency for good cause found and published with the rule.

(e) Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule. Pub.L. 89-554, Sept. 6, 1966, 80 Stat. 383.

5 U.S.C.

§ 706. Scope of review

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings, and conclusions found to be—

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error. Pub.L. 89-554, Sept. 6, 1966, 80 Stat. 393.

APPENDIX E

Statement of Policy Under Review

TITLE 21, CODE OF FEDERAL REGULATION—PART 3
STATEMENTS OF GENERAL POLICY OR INTERPRETATION:
STATUS OF VITAMIN A AND D

Section 3.94

"(a) Vitamin A is an essential nutrient for humans. It is widely recognized that large amounts of vitamin A can cause adverse effects, some of which are serious. The U.S. Recommended Daily Allowance (U.S. RDA) for vitamin A is 1500 International Units, (IU) for infants, 2500 IU for children under 4 years of age, 5000 IU for adults and children 4 or more years of age, and 8000 IU for pregnant or lactating women.

"(b) In view of the toxicity of excessive consumption of vitamin A, the Food and Drug Administration finds that, in order to protect the public health, oral preparations containing vitamin A in excess of 10,000 IU per dosage unit or recommended daily intake are drugs subject to section 503 (b)(1) of the Federal Food, Drug, and Cosmetic Act and shall be restricted to prescription sale. Such products will be regarded as misbranded if at any time prior to dispensing the following conditions are not met:

"(1) The label bears the legend, 'Caution: Federal law prohibits dispensing without a prescription'; and

"(2) The labeling bears full disclosure information as required by §1.106(b)(3)(i) of this chapter, and

especially appropriate warnings regarding vitamin A toxicity.

"(c) Preparations containing 10,000 or less IU of vitamin A per dosage unit will be regarded as misbranded if their recommended daily intake exceeds 10,000 IU."

Section 3.95

"(a) Vitamin D is an essential nutrient for humans. It is widely recognized that vitamin D, when ingested daily in large amounts, is toxic. The U.S. Recommended Daily Allowance (U.S. RDA) for vitamin D is 400 International Units (IU).

"(b) In view of the toxicity of the excessive consumption of vitamin D, the Food and Drug Administration finds that, in order to protect the public health, oral preparations containing vitamin D in excess of 400 IU per dosage unit or recommended daily intake are drugs subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act and shall be restricted to prescription sale. Such products will be regarded as misbranded if at any time prior to dispensing the following conditions are not met:

"(1) The label bears the legend, 'Caution: Federal law prohibits dispensing without a prescription'; and

"(2) The labeling bears full disclosure information as required by §1.106(b)(3)(i) of this chapter, and especially appropriate warnings regarding vitamin D toxicity.

"(c) Preparations containing 400 or less IU of vitamin D per dosage unit will be regarded as misbranded if their recommended daily intake exceeds 400 IU.

"(d) Foods which are represented for use solely under medical supervision to meet nutritional requirements of persons with poor vitamin D absorption may contain vitamin D not in excess of 1000 IU per dosage unit or recommended daily intake."

APPENDIX F

Stenographic Transcript

IN THE
UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WISCONSIN
Case No. 72-CR-109

UNITED STATES OF AMERICA,

Plaintiff,

—vs—

EVERETT FISHERIES, INC., a corporation, and
ERIC E. JOHNSON, an individual,

Defendants.

STENOGRAPHIC TRANSCRIPT

of Ruling by the Court had upon hearing in the above-entitled criminal action in said court, sitting in the City of Madison, in said Western District and State of Wisconsin, the Honorable James E. Doyle, Judge, presiding, on Wednesday, the 30th day of May, 1973, at 10:45 a.m.

APPEARANCES

James M. Bablitch, Assistant United States Attorney, Madison, Wisconsin; Charles J. Raubicheck, Attorney-at-Law, Department of Health, Education & Welfare, Office of the Secretary, Rockville, Maryland, 20852 and Thomas

S. Brett, Attorney-at-Law, U. S. Department of Justice, Washington, D. C., 20530, appeared on behalf of the plaintiff.

John C. Fritschler, Attorney-at-Law, 222 South Hamilton Street, Madison, Wisconsin, 53703, appeared on behalf of the defendants.

PROCEEDINGS

(Whereupon, Ruling by the Court was made in the above-entitled criminal action at 10:45 o'clock a.m. as follows:)

The Court: I will make certain assumptions for the purpose of the Ruling. I will assume for the purpose of this Decision that 21 CFR 128a, Subpart A is a regulation which the Secretary was authorized to promulgate pursuant to 21 U.S.C. Section 371 (a) and also that the regulation was duly promulgated in terms of all procedural requirements.

Also for the purpose of the Ruling I will assume that the regulation is not arbitrary or unreasonable but on the contrary that it is a regulation "for the efficient enforcement of this Chapter" within the meaning of Section 371 of Title 21 of the United States Code.

I understand that the precise question to be decided, that is, the precise question which I intend to decide presently is whether a defendant is guilty of a violation of—Strike that.

The precise question on which I intend to rule is whether these defendants are to be held guilty of the offense charged against them in each of the three counts of the information and, specifically, whether they are to be found guilty

of a violation of Section 331 (a) of Title 21 of the United States Code as a matter of law if the government can prove beyond a reasonable doubt that the defendants violated one or more of the provisions of Section 128a, Subpart A of Title 21 of the Code of Federal Regulations. I decide that the answer to that question is "No".

It is quite clear that the Congress has nowhere provided that it shall be a crime to violate a regulation such as 21 CFR 128a, Subpart A which I have assumed to have been validly promulgated under 21 U.S.C. 371.

The government's contention is, as I understand it, that in administering this criminal prosecution the finder of fact, whether it be a jury or a judge, is to be bound to find the defendant guilty as charged and to find that the food introduced into commerce in each case was adulterated within the meaning of 21 U.S.C. Section 342 (a) (4) if it is shown beyond a reasonable doubt that the food was prepared in a manner which violated in any respect any provision of Subpart A of Section 128a of the Regulations.

I believe that in every criminal case under the sections of the statutes involved here the government must prove beyond a reasonable doubt that the food in question was adulterated and that it was prepared, packed or held under insanitary conditions whereby it may have been rendered injurious to health. And I conclude that in every criminal prosecution under these sections the government must satisfy the finder of fact under proper instructions that these conditions existed.

I conclude that in each case the government must present its evidence so as to persuade the finder of fact and the defense must have its opportunity to dispute and that

the judgement exercised by the Food and Drug Administration in promulgating regulation 128a, Subpart A is not to be given automatic and decisive effect in the case; rather, that the regulations in question are to be given just such effect as the trier of fact may consider that they deserve on the basis of the evidence in the case.

That completes my ruling with respect to that point; and it will be the rule that will apply to further proceedings and the trial in the case.

The defendants have moved to dismiss the information for vagueness. I will declare now that I intend to apply the statute in the case in a manner which other courts have held saves it from vagueness, that is, I will administer the case in such a way that the government will be required to prove beyond a reasonable doubt that the conditions under which the fish was prepared, packed or held were insanitary conditions whereby it may have been rendered injurious to health in the sense that those conditions gave rise to the reasonable probability of contamination. So construed, I hold that the statute is not vague and the motion to dismiss is denied.

I believe that completes my Ruling.

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Appendix F

CERTIFICATE

I, LORETTA PETERS, Official Court Reporter for the United States District Court in and for the Western District of Wisconsin, hereby certify that as such official reporter I was present in said court throughout its sessions, held in the City of Madison, in said Western District and State of Wisconsin, on Wednesday, the 30th day of May, 1973; that I then and there reported by machine shorthand the proceedings had upon hearing then and there held in the above-entitled criminal action; that I thereafter caused to be prepared, under my personal direction, the foregoing typewritten transcript of said proceedings from my original stenographic notes thereof, so taken at said time and place; that the above and foregoing is a full, true and complete transcript of said Ruling by the Court at said time and place, and is the official transcript thereof.

LORETTA PETERS

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In the Supreme Court of the United States

OCTOBER TERM, 1975

No. 74-1383

NATIONAL NUTRITIONAL FOODS ASSOCIATION AND SOLGAR COMPANY, INC., PETITIONERS

v.

CASPAR W. WEINBERGER, SECRETARY OF HEALTH, EDUCATION, AND WELFARE, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF FOR THE RESPONDENTS IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. A-1 to A-32) is reported at 512 F.2d 688.[1] The opinions of the district court (Pet. App. B-1 to B-12, C-1 to C-15) are reported at 366 F.Supp. 1341 and 376 F.Supp. 142.

[1] An earlier decision of the court of appeals affirming the district court's denial of a preliminary injunction is reported at 491 F.2d 845 (C.A. 2).

JURISDICTION

The judgment of the court of appeals was entered on February 3, 1975. The petition for a writ of certiorari was filed on May 2, 1975. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

QUESTIONS PRESENTED

1. Whether the Food and Drug Administration (FDA) may, under Section 701(a) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 371(a), promulgate a regulation classifying oral preparations containing Vitamin A in excess of 10,000 IU (international units) per dosage unit or recommended daily intake, or Vitamin D in excess of 400 IU per dosage unit or recommended daily intake, as "drugs" under Section 201(g) of the Act, 21 U.S.C. 321(g).

2. Whether the "arbitrary, capricious" standard prescribed by 5 U.S.C. 706(2)(A), rather than the "substantial evidence" standard prescribed by 5 U.S.C. 706(2)(E), governs judicial review of regulations adopted in "notice and comment" rule making under 5 U.S.C. 553(c).

3. Whether high dosage forms of a drug that is used by many persons in quantities that have "a potentiality for harmful effect" may be classified as a prescription drug even though such a drug, if labeled with cautionary instructions, might be used safely by persons who follow the cautionary labeling.

STATUTES AND REGULATIONS INVOLVED

The relevant provisions of Sections 201, 502, 503, and 701 of the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040 *et seq.*, as amended, 21 U.S.C. 321, 352, 353, and 371, are set forth in Pet. App. D. The relevant regulations, 21 C.F.R. 3.94 and 21 C.F.R. 3.95, are set forth in Pet. App. E.

STATEMENT

On December 14, 1972, the Commissioner of Food and Drugs commenced a rule-making proceeding by publishing a statement in the Federal Register, 37 Fed. Reg. 26618, giving notice of proposed regulations classifying oral preparations of Vitamins A and D in dosage units or recommended daily quantities in excess of 10,000 IU and 400 IU, respectively, as "drugs" and restricting the sale of such drugs to prescription dispensation pursuant to Section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. 353(b)(1). More than 2,500 written comments (including comments by petitioners) were submitted in response to that notice (Pet. App. A–5). The Commissioner published a report in the Federal Register on August 2, 1973, discussing the comments received and ordering that the regulations become effective on October 1, 1973. See 38 Fed. Reg. 20723.

Petitioners, National Nutritional Foods Association and Solgar Co., Inc., brought suit in the United States District Court for the Southern District of New York on August 6, 1973, seeking declaratory and injunctive

relief to prevent enforcement of the regulations.[2] In April 1974 the district court granted the government's motion for summary judgment and dismissed the complaint (Pet. App. C).

On appeal the United States Court of Appeals for the Second Circuit held that the Commissioner has power to promulgate regulations having the binding force of law under Section 701(a) of the act, 21 U.S.C. 371(a) (Pet. App. A–10 to A–17), and that the Commissioner may utilize the notice-and-comment procedures prescribed by Section 4 of the Administrative Procedure Act, 5 U.S.C. 553(c), in adopting such regulations (*id.* at A–19 to A–21). The court of appeals also rejected petitioners' contention that Section 503(b)(1) of the Act, 21 U.S.C. 353(b)(1) (the "prescription" drug statute) precludes the use of notice-and-comment rule-making procedures for purposes of determining that particular drugs must be sold only on prescription (*id.* at A–17 to A–19). The court ruled that since the "substantial evidence" review standard of 5 U.S.C. 706(2)(E) is restricted to agency action in regard to which an evidentiary hearing is required, the "arbitrary, capricious" standard specified by 5 U.S.C. 706(2)(A) is applicable for purposes of determining the validity of the regulations (*id.* at A–21).

The court of appeals concluded, however, that a "serious question" exists regarding whether the Commissioner had classified properly the higher dosage

[2] Petitioners' request for a preliminary injunction was denied by the district court (366 F. Supp. 1341), and the denial was affirmed by the court of appeals (491 F. 2d 845).

level forms of Vitamins "A" and "D" as "drugs" under Section 201(g), rather than "foods," and remanded the case to the district court for the purpose of conducting a hearing to determine whether that particular determination was rational (*id.* at A–23 to A–24).[3]

ARGUMENT

1. Petitioners' primary contention is that the Commissioner of Food and Drugs had no power to promulgate regulations having binding effect under Section 701(a) of the Act, 21 U.S.C. 371(a).

Section 701(a) provides that "[t]he authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section, is vested in the Secretary."[4] Petitioners argue (Pet. 6–7) that the Commissioner is confined to the issuance of "interpretative" regulations, that is, regulations embodying non-binding statements of agency policy, under Section 701(a), and that any "substantive regulations" must be issued under Section 701(e) of the Act.

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[3] The regulation involved in this case was also challenged in proceedings in the Northern District of Illinois. *National Health Federation* v. *Weinberger*, No. 73–C–2466. The district court dismissed the complaint, and the Seventh Circuit, referring to the present case, affirmed, on the ground that equity jurisdiction should not be invoked where the same issues were pending in litigation in another court. *National Health Federation* v. *Weinberger* (No. 74–1524, decided June 4, 1975).

[4] This authority has been delegated by the Secretary to the Commissioner of Food and Drugs. 21 C.F.R. 2.120(a)(1). See *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 612, n. 2.

Section 701(e) prescribes "* * * an elaborate procedure that must be followed by the FDA in promulgating regulations with respect to certain specifically enumerated subjects * * *" (Pet. App. A–11). Since the classification of a product as a prescription drug is not one of the enumerated categories of Section 701(e), the thrust of petitioners' argument is that the Commissioner cannot proceed by rulemaking, but must deal with the classification of prescription drugs in case-by-case adjudications.[5]

Contrary to petitioners' contention (Pet. 6), their challenge to FDA's rule-making authority under Section 701(a) is not "presented to this Court for the first time" in this case. As the court of appeals recognized, this Court's decisions in *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, and its companion cases, *Ciba Corp.* v. *Weinberger*, 412 U.S. 640, *Weinberger* v. *Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, and *USV Pharmaceutical Corp.* v. *Weinberger*, 412 U.S. 655, interpreted Section 701(a) of the Act to authorize the issuance of binding regulations.

[5] As support for this argument petitioners erroneously assert that in the "prescription drug" statute, 21 U.S.C. 353(b)(1), Congress intended to preclude FDA from issuing binding regulations defining prescription drugs. This contention was correctly rejected by the court of appeals (Pet. App. A–17 to A–18), on whose opinion in this regard we rely. As the court noted, the Senate Report (S. Rep. No. 946, 82d Cong., 1st Sess. 4–5 (1951)), which discussed the version of the bill finally enacted, clearly indicates that FDA was to have the authority "to interpret and enforce" the definition of prescription drugs by the promulgation of regulations under Section 701(a) (Pet. App. A–18 to A–19, n. 10).

Thus, in *Weinberger* v. *Bentex Pharmaceuticals, Inc., supra,* this Court held that the Commissioner has power to determine the "new drug" status of particular drugs in administrative proceedings and rejected the contention that such determination must be made on a case-by-case basis in judicial proceedings to enjoin distribution of a product that FDA alleges to be a new drug. This Court said: "We think that it is implicit in the regulatory scheme, not spelled out *in haec verba,* that FDA has jurisdiction to decide with administrative finality, subject to the types of judicial review provided, the 'new drug' status of individual drugs or classes of drugs. The deluge of litigation that would follow if 'me-too' drugs and OTC drugs had to receive *de novo* hearings in the courts would inure to the interests of manufacturers and merchants in drugs, but not to the interests of the public that Congress was anxious to protect * * * ." 412 U.S. at 653.

Petitioners' contention that prescription status of products must be determined in adjudicatory proceedings is essentially identical to the argument rejected in *Bentex Pharmaceuticals, Inc., supra.* The same considerations that underlie that decision are equally applicable here.[6]

[6] The court of appeals noted (Pet. App. A–13) that the interpretative-substantive dichotomy that petitioner urges is not a useful analytical concept. The correctness of that observation is demonstrated by petitioners' attempt to distinguish *Weinberger* v. *Hynson, Westcott & Dunning, Inc., supra,* as involving only an "interpretation" or "agency policy" (Pet. 11). The regulations upheld in *Hynson,* which, like the regulations involved here, were promulgated pursuant to Section 701(a), " 'provide the basis for

2. The court of appeals, application of the 'arbitrary, capricious" standard in determining the validity of the regulations does not conflict with this Court's decision in *Abbott Laboratories* v. *Gardner,* 387 U.S. 136, as petitioners suggest (Pet. 11). *Abbott Laboratories* held that certain FDA regulations may be challenged in preënforcement declaratory judgment suits as well as in enforcement proceedings. The *Abbott Laboratories* opinion does not discuss the standard of review to be applied in determining the validity of a Section 701(a) regulation in either a preënforcement suit or an enforcement action, and does not imply that any standard other than the "arbitrary, capricious" standard is to be employed.

Petitioners incorrectly assert that this Court is now confronted "for the first time" with resolving the question of "the appropriate scope of review for all substantive agency action" (Pet. 19). This Court has held that the application of the "substantial evidence" standard of 5 U.S.C. 706(2)(E) is restricted to those cases "subject to the hearing provisions of 5 U.S.C. §§ 556 and 557 or 'otherwise reviewed on the record of an agency hearing provided by statute . . .' 5 U.S.C. § 706(2)(E)." *Weinberger* v. *Hynson, Westcott & Dunning, Inc., supra,* 412 U.S. at 622, n. 19. Since no evidentiary hearing is required in rule-making proceedings under Section 701(a) of the Act,[7] the

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the determination whether there is 'substantial evidence' to support the claims of effectiveness for 'new drugs' * * *" (412 U.S. at 618), and, however petitioner would describe them, they have binding effect.

court of appeals correctly held that the "arbitrary, capricious" standard of 5 U.S.C. 706(2)(A) is the applicable standard of review for this regulation.

3. Under the "prescription drug" statute, 21 U.S.C. 353(b)(1)(B), a drug can be classified as a prescription drug if "because of its toxicity or other potentiality for harmful effect, or the method of its use" it "is not safe for use except under the supervision of a practitioner licensed * * * to administer such drug." The court of appeals correctly rejected the petitioners' contention (Pet. 19–21) that a drug can never be classified as a prescription drug if it can be safely used by persons who follow the cautionary labelling. The court of appeals properly concluded that it "was reasonable for the Commissioner to recognize that the risks of toxicity are increased by over-the-counter availability of readily ingestible, high dosage forms" (Pet. App. A–28) and noted that FDA "was not confronted with a case in which there was the mere possibility that a drug would be occasionally misused, but one in which the actual way in which the product is apparently used on a normal basis by many persons presents serious risks of toxicity" (Pet. App. A–29).

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[7] The Administrative Procedure Act does require that an agency afford notice and an opportunity for interested persons to participate in rule-making proceedings "through submission of written data, views, or arguments *with or without opportunity for oral presentation*" (emphasis added). 5 U.S.C. 553(c). These requirements were satisfied here (see Pet. App. A–3 to A–6, A–19 to A–21). See also the court of appeals' opinion affirming the district court's denial of a preliminary injunction in this case. 491 F. 2d 845, 846 (C.A. 2).

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be denied.

Respectfully submitted.

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